

ANNUAL ACTIVITY REPORT OF THE
EUROPEAN FOOD SAFETY AUTHORITY FOR 2008

Document describing the activities of the Authority in 2008

Adopted in Rome, Italy
on January 29, 2009

Signed by
Diána Bánáti
Chair

CONTENTS

I Highlights	3
II Provide scientific opinions and advice to the European Commission, the European Parliament and the Member States	4
II.1 Overview	
II.2 Risk Assessment	
II.3 Scientific Committee	
II.4 Scientific Cooperation & Assistance	
III Enhance risk assessment methodologies and coordinate scientific networks	12
III.1 Overview	
III.2 Scientific Committee	
III.3 Scientific Cooperation & Assistance	
III.4 Risk Assessment	
IV Communicate scientific advice and facilitate dialogue with interested parties	20
IV.1 Communications overview	
IV.2 Dialogue with Member States: Advisory Forum	
IV.3 Relations with European institutions and agencies	
IV.4 International relations	
IV.5 Stakeholder activities	
IV.6 Italian authorities	
V Manage and provide administrative support	25
V.1 Overview	
V.2 Human Resource Policies	
V.3 Career development	
V.4 Recruitment	
V.5 Working Environment	
V.6 Legal and policy affairs	
V.7 Finance and accounts	
V.8 Information Technology & Operations	
V.9 Quality Management	
VI Annexes	32
Annex 1: Budget Execution	
Annex 2: Establishment Plan	
Annex 3: Declaration of Assurance	
Annex 4: Report on the Implementation of the Internal Control Standards	
Annex 5: List of Negotiated Procedures	
Annex 6: Glossary of Abbreviations	

I Highlights

Corporate

- ◆ European Commissioner for Health, Androulla Vassiliou, visits EFSA (p. 22)
- ◆ Membership of EFSA's Management Board is renewed
- ◆ EFSA's Strategic Plan 2009-2013 is launched
- ◆ Joint symposium on climate change with FAO and WHO in Rome to mark World Food Day (p. 24)
- ◆ 489 scientific outputs are adopted (pp. 11, 20)
- ◆ Roadmap on priorities and deadlines agreed with Commission (p. 23)

Risk Assessment and Scientific Advice

- ◆ Animal cloning: a public consultation is launched prior to adoption of EFSA opinion (p. 10)
- ◆ Opinions on nutritional profiles and first opinions on health claims are adopted (p. 9)
- ◆ Fast-track advice is issued on contaminated sunflower oil, melamine and dioxins (p. 8)
- ◆ Nanotechnology: a public consultation is launched for draft opinion (p. 10)
- ◆ Bisphenol A: EFSA reviews latest data on human toxicokinetics (p. 6)
- ◆ Food additives and hyperactivity: EFSA evaluates the "Southampton study" (p. 6)
- ◆ Risk-benefit assessment of nitrate in vegetables is published (p. 7)
- ◆ Guidance Document on risk assessment for birds and mammals is issued by PPR Panel (p. 9)
- ◆ Fish welfare opinions are adopted (p. 6)
- ◆ EFSA provides scientific advice on implementation of BSE/TSE roadmap (p. 7)
- ◆ AFC Panel is replaced with ANS and CEF Panels (p. 6)
- ◆ Technical Guidance Documents for feed additive applications are adopted (p. 18)

Scientific Cooperation

- ◆ European food consumption database is launched (p. 14)
- ◆ Pesticide peer review: stages 3 and 4 are completed (p. 10)
- ◆ Focal Points: all agreements are finalised (p. 16)
- ◆ Colony Collapse Disorder: EFSA's Assessment Methodology Unit reports on bee mortality (p. 14)
- ◆ Community summary reports on *Campylobacter* and *Salmonella* are published (p. 16)
- ◆ EFSA's expert database is launched (p. 16)
- ◆ Scientific colloquia are held on acrylamide carcinogenicity and *Campylobacter* (p. 16)

Communication

- ◆ Significant increase in media coverage of EFSA: 62% increase in 2008 (p. 22)
- ◆ Increased coherence in communications on key issues such as TSE, bisphenol A and cloning (p. 20)
- ◆ Increased transparency in risk assessment process: graphical presentation of risk assessment workflow is published on EFSA website (p. 21); online database for Declarations of Interest is launched (p. 5)
- ◆ New targeted newsletters (food, animals, plants) are launched (p. 21)
- ◆ Publication of articles by EFSA staff in scientific journals (p. 20)
- ◆ Six joint events are held with several Member States as well as local events in Parma (p. 21)
- ◆ Media interviews: 123 in 2008 vs. 44 in 2007 (p. 22)

Administration

- ◆ Budget execution of 97% is achieved (p. 28)
- ◆ New staff policies are issued: flexible working, staff policy plan, prevention of harassment (p. 25)
- ◆ Modernisation of the financial system (p. 28)
- ◆ Establishment Plan: staff numbers increase to 395 (p. 33)
- ◆ Liaison with the Italian authorities on settlement issues is intensified (p. 25)

II Provide scientific opinions and advice to the European Commission, the European Parliament and the Member States (Activity 1)

II.1 Overview

A total of 360 scientific outputs¹ for activity 1 were adopted in 2008 compared with 204 opinions and 20 PRAPeR conclusions in 2007. The workload for the Panels remained high and particular increases were seen in the area of applications where the highest number of new requests was related to health claims. Approximately 84% of scientific opinions were adopted in time, with most delays occurring in the area covered by the former AFC Panel. This was mainly due to the high number of applications received during previous years. Monitoring and planning tools were developed to support the prioritisation of the work. Coordination of priorities with the Commission helped EFSA to focus on the most urgent requests.

To increase support to the Panels, several initiatives were taken: staffing levels were significantly increased for Units working on applications; more activities were outsourced through contracts and grants (€2.3 m in 2008 vs. €1.6 m in 2007 for activity 1); the number of external experts supporting the Panels in Working Groups was increased; and the support provided by the Scientific Cooperation & Assistance (SCA) Directorate was enhanced, especially in the area of data collection and statistics. Many Panels also produced guidance documents for applications and risk assessment methodologies to support applicants and increase the transparency of the risk assessment process. In addition, to reduce the experts' travel burden, more than 50% of meetings of Scientific Panels or their Working Groups were held outside Parma compared with 42% in 2007.

In order to cope with the workload, the AFC Panel was replaced on 10 July 2008 by two new Panels, ANS and CEF, which took over the significant workload in the area of nutrient sources used for food supplements, food additives, food contact materials and flavourings. In addition, the Panels were kept busy with evaluations of scientific developments in food colours and bisphenol A.

The AHAW Panel updated its opinions on Avian Influenza and Bluetongue and published five opinions on the welfare of fish. The BIOHAZ Panel developed further the use of quantitative microbiological risk assessment for *Campylobacter* and *Salmonella* and gave opinions to help risk managers in their decision making, as outlined in the BSE/TSE roadmap, and for *ad hoc* questions such as TSE in milk of small ruminants.

The CONTAM Panel issued a first detailed European overview of two emerging compounds, perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) and an opinion on a risk-benefit analysis of nitrate in vegetables. In addition, the CONTAM Unit provided fast-track responses on sunflower oil contamination, melamine in Chinese composite foods and dioxin contamination of Irish pigmeat, the latter two jointly with the DATEX Unit, enabling the European Commission to take timely measures to safeguard public health. The FEEDAP Panel adopted 21 opinions in the framework of Regulation (EC) No 1831/2003 and a generic opinion on vitamin A.

Although the GMO Panel was able to adopt all the scientific opinions on applications within the legal deadlines, there was an increased demand for generic opinions such as the mandates received from the European Commission for Safeguard Clauses (Article 23 of Directive 2001/18/EC) as well as requests for scientific advice related to previously adopted application opinions. Much of the work of the NDA Panel concerned the implementation of EU Regulation on Nutrition and Health Claims where the Panel adopted an opinion on scientific criteria to be considered when establishing nutrient profiles, adopted the first opinions

¹This includes a small number of co-adoption between different Scientific Panels. For a definition of EFSA scientific outputs, see: http://www.efsa.europa.eu/EFSA/ScientificOpinionPublicationReport/efsa_locale-1178620753812_1211902186929.htm.

on Article 14 health claims and started work on over 4000 main claim entries under Article 13. The Panel also adopted opinions on novel foods.

The PLH Panel published scientific evaluations of 30 pest risk assessments documents (PRAs) for French overseas departments and evaluated PRAs provided by South Africa (citrus black spot). The PPR Panel finalised an opinion on the science behind the Guidance Document on risk assessment for birds and mammals and an evaluation of the suitability of existing methodologies and the identification of new approaches to assess cumulative and synergic risks to human health of pesticides. In addition, it issued opinions based on requests from PRAPeR.

In the scientific review of plant protection products, 2008 was a critical year for the PRAPeR Unit. The workload associated for the review of existing substances was 2.5 times higher than 2007, with several new tasks. To manage the workload, team leaders were appointed for each of the major fields, the coordination group was strengthened substantially, extra Working Group meetings were held, regular meetings were held with the Commission and Member States to review the work programme, and a Working Group was established to review the current pesticide safety review system.

Particular attention was focused on implementing the Management Board decision (11 September 2007) on accelerated procedures for scientific advice. The fast-track procedures were utilised in the incidents associated with contaminated sunflower oil from the Ukraine, melamine in composite foods from China and dioxins in Irish pigmeat.

The transparency of EFSA's scientific work was also prioritised. The workflow of the risk assessment process was published on the EFSA website and the Management Board decision on the declarations of interest (DoI) policy (11 September 2007) was implemented. Since the Dols involve over 700 experts (for Activity 1 only) in the Scientific Committee, Panels and their Working Groups annually, an IT tool was developed to support the experts and the internal screening process.

The quality of scientific outputs received special attention and the implementation of EFSA's quality assurance system via the INEX (internal and external review) process was started by self-evaluation of all scientific outputs and an internal evaluation of randomly selected outputs. The implementation plan for the external evaluation, to be initiated in 2009, was also drafted. A weekly Mandates Review Committee, including the Executive Director and the Directors of Risk Assessment, Scientific Cooperation & Assistance and Communication and the Head of Legal and Policy Affairs, was established in order to analyse all requests to EFSA, and address them in an integrated manner. In addition, several other elements for strengthening quality assurance were established: documentation of workflows, creation of Standard Operating Procedures (SOPs), and finalisation of key definitions in order to harmonise activities.

Communication was also an important feature of this activity and EFSA responded to more than 670 queries related to risk communication in 2008. Nearly 20% of EFSA scientific opinions were supported by communications activities and around 90% of EFSA-related media coverage was on scientific issues compared with 81% and 79% in 2007 and 2006, respectively. To target the communication to a scientific audience, EFSA gave 158 lectures in scientific events and published 39 papers in the scientific literature.

Some opinions scheduled for adoption in 2008 were delayed for a variety of reasons: reprioritisation with the European Commission, further information required, clock stops etc. Conversely, many unscheduled activities, such as responding to requests for urgent advice, were undertaken.

II.2 Risk Assessment

Food additives, nutrient sources, enzymes, flavourings, processing aids and materials in contact with food

The AFC Panel was replaced on 10 July 2008 by the Panel on food additives and nutrient sources added to food (ANS) and the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) and its activities were transferred to these new Panels. While the AFC Panel was operational in 2008 it adopted: 6 opinions and one statement on nutrient sources corresponding to 148 dossiers; 41 opinions on flavourings corresponding to 360 substances; 4 opinions on food additives including the opinion on the "Southampton study" (on the association of childhood hyperactivity and certain food colours); 8 opinions on food contact materials; one opinion on oxyhydroxide media for treatment of mineral waters; and one opinion on the toxicokinetics of bisphenol A.

The ANS Panel took on responsibility for the fields of food additives and nutrient sources added to food. Most of the mandates relate to the risk assessment of regulated substances and products. The Panel prioritised the evaluation of the remaining nutrient sources for food supplements (181 application dossiers) by the end of May 2009. In order to accelerate the evaluation process, the former Working Group on food additives of the AFC Panel was replaced by two Working Groups on additives and nutrient sources. Two procurement contracts were signed for the preparation of a number of pre-assessment documents to facilitate the preparation of opinions. The ANS Panel adopted 10 opinions and 2 statements corresponding to 34 application dossiers for nutrient sources in 2008. The rest of the applications for nutrient sources in food supplements are scheduled for evaluation by May 2009. The re-evaluation of the 6 colours used in the Southampton study (of which 5 are azo colours) has been prioritised and is planned to be finalised by the ANS Panel by June 2009. The re-evaluation of 5 other azo colours is scheduled for March 2010. For the latter, discussions have taken place with the NDA Panel to organise the work on the evaluation of the allergenicity of the colours because this aspect is covered by a new mandate from the European Commission. In light of the priorities agreed with the Commission, i.e. nutrient sources and colours, work on other food additives was postponed and will be addressed after completion of the evaluation of nutrient sources.

The CEF Panel took on responsibility for the food contact materials, enzymes, flavourings and processing aids aspects of the former AFC Panel's mandate. The work of CEF is prepared in five standing Working Groups. EFSA has a mandate to evaluate flavouring substances on the Community Register. This programme is ongoing, with a deadline of 31 December 2009 agreed with the Commission Services. A total of 660 substances were evaluated in 2008 (360 by AFC, 300 by CEF). For 500 substances, the conclusion of the evaluation was that additional data are needed. The CEF Panel prioritised substances with structural alerts for genotoxicity (Flavouring Group "FGE.19"). A test strategy for these compounds was established, associated with a list of representative substances to be tested. The CEF Panel continued the work which had been started by the AFC Panel on the evaluation of smoke flavourings. EFSA has a mandate to evaluate substances used to manufacture materials for contact with foodstuffs (FCM). EFSA has received 11 applications for new substances and 33 for re-evaluations. The first application for a recycling process was also received. The AFC and CEF Panels published respectively an opinion and two statements concerning the potential risk to public health of bisphenol A.

Animal health and welfare

The AHAW Panel adopted 12 scientific opinions on generic questions, 7 on animal diseases (tuberculosis, avian influenza, aquatic diseases and susceptible species, Bluetongue and classical swine fever) and 5 on animal welfare issues. During 2008, the AHAW Unit strengthened its collaboration with the European Commission, the Community Reference Laboratories (CRL) and Member States. The Unit analysed its main lines of communications with Member States to explore synergies in relation to animal diseases and welfare in line with the Community Strategy on Animal Health and the paper on the "Role of EFSA in Animal Health".

One meeting was held with Member States in the framework of the Advisory Forum on future collaboration on animal health and welfare. A total of 4 calls were launched under Article 36, three on emerging animal and aquatic diseases and one on risk assessment methodologies for the welfare of food-producing animals during transport.

Biological hazards

The BIOHAZ Panel adopted 15 outputs (12 scientific opinions and 3 other reports), including 7 on BSE/TSE issues and 2 related to animal by-products. As *Campylobacter* and *Salmonella* are the most common causes of zoonotic infections in the EU, a number of issues regarding *Salmonella* are being addressed, some of which will continue for a number of years. From EC regulation 2160/2003, and further to the aim of developing quantitative risk assessment methodologies at an EU level, quantitative microbiological risk assessments (QMRAs) on *Salmonella* in poultry breeder flocks were carried out. Further QMRAs were initiated for broiler and layer flocks. A first EU-wide full QMRA on *Salmonella* in slaughter and breeding pigs, funded through Article 36, was started in 2008. To build on existing experience within the EU, two workshops were held to gain information on existing related QMRA studies carried out in Member States, and to analyse the availability of data for an EU-wide study.

With regards to *Campylobacter*, work was started on a quantitative risk assessment of broiler meat, the most important source for human infections. Antimicrobial resistance was a significant feature of 2008 for the BIOHAZ Panel. EFSA received a joint mandate with EMEA and ECDC from the European Commission on antimicrobial resistance. Self-tasking opinions on the transmission of antimicrobial resistance hazards via food, as well as on the human health implications of methicillin-resistant *Staphylococcus aureus* (MRSA) in animals and food were completed, as well as an assessment of the possible effect of antimicrobial treatments on the disinfection of poultry carcasses. The role of feed as a source of microbiological hazards was assessed, and the BIOHAZ Panel continues to collaborate with the AHAW Panel on food safety consequences from animal health and welfare issues (e.g. fish welfare).

Prion diseases, whilst of decreasing prominence, continue to be an important issue for the BIOHAZ Panel, as outlined in the BSE/TSE roadmap. In the context of the declining BSE epidemic, existing monitoring regimes have been reviewed. As new information became available, risks from other TSEs, for example through the meat and milk of small ruminants, were assessed. In relation to the assessment of milk from small ruminants, coordination with the French Food Safety Agency (AFSSA) was implemented at an early stage to avoid unnecessary divergence of opinions. EFSA also started a new series of TSE test evaluations.

Contaminants

The CONTAM Panel and CONTAM Unit issued 19 scientific opinions and statements related to contaminants in foods and feeds in 2008 to assess the impact on European public health and animal health.

With regard to food contaminants, the Panel:

- Proposed a broader set of polycyclic aromatic hydrocarbon compounds for inclusion in the current legislation
- Alerted risk managers that the current maximum limits for some marine biotoxins in shellfish, as well as the prescribed animal detection test, might be inadequate to protect public health
- Issued a first detailed European overview of two emerging compounds, perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA)
- Issued a risk-benefit analysis of nitrate in vegetables

The Panel finalised its evaluation of the risks to animal and public health of unavoidable cross-contamination of non-target feeds with authorised coccidiostats and issued several opinions on undesirable substances in animal feed. This work enabled the European Commission to set or revise the current legal measures in Europe. The Panel started work on risk assessments of cadmium, lead, arsenic and uranium in food and

undesirable substances such as nitrite and saponins in animal feed. It is anticipated that these requests will be finalised in 2009.

In addition, the CONTAM Unit provided fast-track responses on sunflower oil contamination, melamine in Chinese composite foods and dioxin contamination of Irish pigmeat, the latter two jointly with the DATEX Unit, enabling the European Commission to take timely measures to safeguard public health. The CONTAM Unit launched two successful Article 36 calls: the mycotoxins call was designed to enhance the efficiency of future mandates while the call on veterinary medicinal products in Third Countries was in preparation for new legislation on residue limits of pharmacologically active substances in foodstuffs of animal origin. The scientific staff of the CONTAM Unit was actively involved in the dissemination of its work in the scientific and regulatory areas, publishing 7 scientific papers and giving 16 presentations.

Feed additives

The FEEDAP Panel adopted 21 opinions in the framework of Regulation (EC) No 1831/2003, including 16 opinions under Article 4(1) (evaluation of new products/extension of use), 4 under Article 13(3) (modifications of the terms of the authorisation), and one under Article 25(1). The FEEDAP Panel also received 5 requests for scientific opinions and adopted 3 opinions under Regulation (EC) No 178/2002, following negative opinions from the FEEDAP Panel. It also adopted a generic opinion on vitamin A. Of the questions received in 2008, 15 were submitted for re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 and one was received under Regulation (EC) No 1829/2003 (bacterial biomasses produced by genetically modified microorganisms) which are under evaluation.

During 2008, the FEEDAP Unit worked closely with the European Commission, the CRL and Member States to establish a detailed calendar with a 'priority list' for the re-evaluation of all existing feed additives in accordance with Article 10 of Regulation (EC) No 1831/2003; EFSA's proposal for prioritisation was accepted by the European Commission and Member States. The deadline for the submission of applications for re-evaluation is 8 November 2010. In 2008, seven meetings were held with industry associations/applicants (e.g. FEFANA, EMFEMA, IFAH, Elanco, Novus Europe and DSM) to discuss issues related to applications.

Genetically modified organisms

The number of application dossiers received by EFSA remained constant at approximately one per month. However, since the demand for generic and guidance opinions significantly increased in 2008, the Panel has therefore not adopted as many opinions as planned; however all the adopted opinions met the legal deadlines. The Panel adopted 10 scientific opinions on applications for placing on the market of GM plants within Regulation (EC) No 1829/2003 as well as co-adoption with the FEEDAP (within Regulation (EC) No 1831/2003) and NDA Panels (within Regulation (EC) No 178/2002 and Regulation (EC) No 258/97). To address the workload, staff numbers in the GMO Unit were increased from 11 to 23. The following tasks were prioritised: reduction in the time taken for completeness checking to 6 weeks; provision of more support to the Panel; and enhanced interaction with Member States and applicants. The Unit provided support to the European Commission by presenting adopted opinions to the Standing Committee of the Food Chain and Animal Health and during two meetings with the Office of the United States Trade Representative (USTR) in relation to the WTO Panel on GMOs.

The 12 generic mandates received from the European Commission in 2008 were in relation to the evaluation of information submitted in support of Safeguard Clauses (7 mandates) invoked by Member States (Article 23 of Directive 2001/18/EC), as well as other requests (5 mandates) for scientific advice related to previously adopted application opinions; the GMO Panel adopted 6 generic opinions and 1 statement on these within the deadline. Due to problems in setting up bilateral meetings with Austria, 3 Austrian Safeguard Clauses are still pending and have deadlines at the end of March 2009. In addition, one

request for scientific advice related to antibiotic resistance marker genes was postponed until March 2009 due to the complexity of the topic.

Dietetic products, nutrition and allergies

Much of the work of the NDA Panel concerned the implementation of the EU Regulation on Nutrition and Health Claims. The Panel adopted an opinion on scientific criteria to be considered when establishing nutrient profiles. This advice has been taken up by risk managers who are responsible for establishing nutrient profiles by 2010. During the year, EFSA received 236 Article 14 health claim applications: 90% related to child health claims and 10% to disease reduction claims. A total of 38 opinions were adopted in 2008 covering 45 applications. EFSA also received claims under Article 13.5 based on newly developed science and/or proprietary data and adopted 5 opinions in this area. With respect to Article 13.1 functional claims, Member States submitted to the European Commission around 44,000 claims and in July EFSA received a draft consolidated list of around 3000 claims to evaluate for possible inclusion in a community list of permitted health claims. In November and December, EFSA received a further 1200 claims for evaluation. EFSA pre-screened the list and will return to the Commission in early 2009 those claims for which more clarification or further information are needed. The deadline for claims received in July 2008, to which no changes were made in subsequent lists and which passed pre-screening, is July 2009. To manage the workload, the number of staff in the NDA Unit was more than doubled in 2008.

In the context of providing scientific advice on dietary reference values, the Panel launched public consultations on draft opinions on food-based dietary guidelines, general principles of deriving and applying dietary reference values and dietary reference values for water. The public consultations were open until end-December 2008. Draft opinions on dietary reference values for energy, carbohydrates, fibres, fats and protein were drafted for public consultation in early 2009. All opinions will be finalised in 2009.

In the area of the safety assessment of Novel Foods, the NDA Panel received 7 additional applications and adopted 8 opinions related to, for example, lycopenes, fungal oil, ice-structuring protein, noni products, zeaxanthin, chia seed, krill oil and alfalfa. With the anticipated revision of the Novel Foods Regulation, it is expected that the NDA Panel will receive more applications annually. The NDA Panel also adopted an opinion on the safety, bioavailability and suitability of lutein for use by infants and young children.

Plant health

In response to Commission requests, the PLH Panel:

- Finalised the scientific evaluation of 30 pest risk assessments documents (PRAs) made by France on organisms considered by France harmful to citrus and banana crops in four French overseas departments
- Adopted a scientific opinion on the pest risk assessment and additional supporting evidence provided by South Africa on *Guignardia citricarpa* (citrus black spot; the mandate included a specific request to identify management options additional to those in regulation 2000/29/EC)
- Evaluated the UK's PRA of the oak processionary moth (*Thaumetopoea processionea*)

To increase the scientific quality of Panel outputs, enhanced modelling was used in collaboration with the Joint Research Centre at Ispra.

Plant protection products and their residues

The PPR Panel adopted the following opinions:

- The science behind the Guidance Document on risk assessment for birds and mammals
- Evaluation of the suitability of existing methodologies and the identification of new approaches to assess cumulative and synergic risks to human health of pesticides
- Developmental neurotoxicology of deltamethrin

- The relative utility of total concentration and pore water concentration as exposure metrics in the assessment of ecotoxicological risks from pesticides and their metabolites in soil

In addition, the Panel worked on an opinion on the cumulative exposure assessment of triazole fungicides (case study). The PPR Panel continued to cooperate with the European Commission via the Standing Committee of the Food Chain and Animal Health-Plant Protection Products (for example on the decision for inclusion of deltamethrin in Annex I of the Directive 91/414/EEC). Opinions of the PPR Panel were taken into consideration for an EU position developed by DG Health and Consumers and impacted on subsequent Codex Alimentarius decisions.

II.3 Scientific Committee

The Scientific Committee finalised and adopted an opinion on the implications of animal cloning for food safety, animal health and welfare, and the environment. The draft opinion was subject to public consultation. An opinion was drafted on the need for specific risk assessment approaches of applications of nanotechnologies in the food and feed area including the identification of the nature of possible hazards associated with the actual and foreseen applications in the food and feed area. The draft opinion was subject to a public consultation and will be finalised and adopted by February 2009.

II.4 Scientific Cooperation & Assistance

Assessment Methodology

For this activity, the Assessment Methodology Unit (AMU) spent most of its resources on the provision of scientific support on risk assessment methodology issues (in particular for the BIOHAZ, CONTAM and PLH Panels), data management (BIOHAZ), epidemiological analysis (BIOHAZ) and statistical analysis (AFC, ANS, BIOHAZ, GMO, PLH, and PPR). This included toxicokinetic and benchmark dose modelling activities, with technical reports and written contributions to opinions to support the CONTAM Panel. AMU contributed to the Working Group that evaluated the *Lancet* publication on the effects of certain food additives on child behaviour (Southampton study). After an initial review of the paper and the Food Standards Agency report, the Unit re-analysed the raw data from the authors and issued a statistical report to the AFC Panel's Working Group. Results from that report were used in the opinion prepared by the Working Group and the opinion, together with the statistical report, was adopted at the AFC plenary meeting in March.

In collaboration with some members of the CEF Panel, AMU co-authored an EFSA statement on the assessment of the implications to the hazard and risk assessment of bisphenol A (BPA) of a recently published study correlating urinary BPA concentrations to medical disorders in adults.

Pesticide risk assessment peer review

The European Commission consulted EFSA on 60 substances in stages 3 and 4 of the EU pesticide review programme of existing active substances. PRAPeR organised a peer review comprising the following stages:

- Feedback on the draft assessment report from Member States, applicants, the public and PRAPeR
- Organisation of 6 rounds of meetings involving 5 different groups of experts.
- Drafting EFSA's conclusions which are used by the European Commission as a basis for the decision-making for inclusion or non-inclusion in the Community's list of active substances

EFSA was consulted by the European Commission concerning the re-submission for Annex I inclusion of 3 existing active substances, after an initial non-inclusion decision. For one of these, a conclusion was delivered while for the other two the process is ongoing.

In addition, a Working Group of risk assessors and risk managers from the Members States and the Commission was organised, which was chaired by EFSA and met several times in order to review the efficiency of the EU peer review process.

Table 1. Number of outputs in 2008 for Activity 1.

	SC	AFC	AH AW	ANS	BIO HAZ	CEF	CON TAM	FEE DAP	GMO	ND A	PP R	PLH	PRAP eR	Total	Target 2008*
Opinions on applications	0	51	0	10	2	16	0	24	10	52	0	0	0	165	221
Generic opinions	1	3	12	0	10	0	15	1	6	1	4	31	62	146	166
Statements	0	1	1	2	0	3	4	0	1	0	0	0	0	12	11
Other technical and scientific reports	1	0	0	0	1	0	0	0	0	0	34	0	1	37	7
Total scientific outputs	2	55	13	12	13	19	19	25	17	53	38	31	63	360	405
Contracts and Grants	0	7	7	3	2	7	2	3	0	1	1	3	0	36	
Plenary meetings	5	5	7	3	8	3	5	9	8	5	5	7	1	71	
WG Meetings	18	19	123	6	57	11	49	60	44	36	24	45	29	521	
Meetings with third parties (stakeholders, MS etc)	5	1	1	0	6	4	1	9	24	20	7	7	30	115	
Public consultations	3	1	0	0	1	0	0	0	0	3	0	0	18	26	
Presentations, lectures etc	12	3	30	0	15	4	16	3	11	20	11	18	17	160	
Papers in scientific literature	1	1	10	0	10	1	7	0	4	5	1	0	0	40	
Queries from communication and LPA	3	30	3	50	33	30	74	40	55	270	9	0	14	611	
Others	0	0	1	0	0	0	0	0	1	0	0	2	0	4	

* Targets were reviewed in July 2008 in consultation with the European Commission. In addition the nomenclature for classification of EFSA outputs was formalised in 2008.

Activity 1	Unit	2008 Budget	Staff	2008 Personnel Expenditure	2008 Infrastructure Expenditure	2008 Operational Expenditure	2008 Total Expenditure	%
Activity 1	ANS	1,5	10	0,8	0,2	0,4	1,4	96%
	CEF	1,9	9	0,7	0,2	0,9	1,8	95%
	FEEDAP	2,5	16	1,3	0,4	0,8	2,5	98%
	PLH	1,5	7	0,6	0,2	0,7	1,4	98%
	PPR	1,4	9	0,7	0,2	0,4	1,4	96%
	GMO	2,4	17	1,3	0,4	0,6	2,3	97%
	NDA	2,0	14	1,1	0,3	0,4	1,9	96%
	BIOHAZ	2,7	12	1,0	0,3	1,4	2,6	97%
	CONTAM	1,4	7	0,6	0,2	0,6	1,3	95%
	AHAW	3,5	18	1,4	0,4	1,5	3,4	96%
	Praper	4,5	31	2,5	0,8	1,1	4,3	96%
	Zoonoses	1,7	12	1,0	0,3	0,4	1,7	97%
	Other SCA	4,3	13	1,0	0,3	2,9	4,2	98%
	Other	1,1	10	0,8	0,2	0,0	1,0	98%
TOTAL		32,3	185	14,7	4,6	12,0	31,3	97%

III Enhance risk assessment methodologies and coordinate scientific networks (Activity 2)

III.1 Overview

The number of tasks carried out in the area of data collection expanded considerably in 2008 and the total number of scientific outputs was 129. Not only have the number of zoonoses-related data collection activities increased but PRAPeR has taken responsibility for the annual report on pesticide residues. Critically, the Advisory Forum and the Scientific Committee both endorsed the priorities identified in the paper on the Strategy on Data Collection for Exposure. This means that, in line with its Founding Regulation and with the support of the Commission, EFSA is responsible for the coordination of data collection in relation to food consumption, chemical occurrence and food composition. These tasks are carried out by the DATEX Unit, which has expanded substantially in 2008 to accommodate the new tasks, and has launched several calls.

Data management and analyses, including exposure assessments, were significant aspects of the work of the SCA Units, as was the drafting of reports that were submitted for review and adoption to the relevant Scientific Panel or Member State network. The framework contract for data management and statistical analysis has proven to be very valuable. Member States are supportive of EFSA's data collection initiatives but want access to the data and no duplication of submission to EFSA, the Commission, or other organisations such as the WHO. Furthermore, the use of multiple databases for exposure assessment highlights the need for the creation by EFSA, in collaboration with Member States, of a common framework for data transfer and storage. This is a major challenge for the SCA Directorate and particularly for the DATEX Unit.

Other projects requiring modelling of microbiological or chemical data were handled by the AMU Unit which responded effectively to requests for support from the Scientific Panels and the Scientific Committee. AMU will be challenged to support the assessment of a wide variety of toxicological data and, to this end, a number of initiatives have already been taken to make available internal and external resources.

EFSA's mandate on emerging risks was formally implemented through the establishment of the Emerging Risks Unit in 2008. Due to the challenging nature of this field and the lack of established approaches,

substantial effort was devoted to achieving consensus with the Scientific Committee, the Panels, and Member States on identifying existing work in the field and on the objectives and key deliverables of the Unit e.g. collaboration on the RASFF. The Unit must have access to databases on hazards and exposure and it will take a leading role on the former within SCA. It should also be noted that, within SCA, it is the AMU Unit, rather than the Emerging Risks Unit, that is evolving towards taking a coordinating role in emerging issues in plants and animals, including animal welfare. Two crisis exercises were held, including one outside Parma, and the Crisis Manual was updated.

During 2008, the Scientific Cooperation (SCO) Unit, which operates as the day-to-day interface for scientific cooperation with the Member States, became fully operational. It has already been successful in fostering closer cooperation between EFSA and Member States and feedback from Member States on the implementation of the strategy of cooperation indicates that it is important to continue along this course. The challenge is that the demands on the Focal Points are high and are expected to grow as Member States have requested that the levels of cooperation be expanded.

In order to complete the review of the 3rd and 4th stage pesticide active substances on time, there was only limited time available to handle new active substances. This issue will receive higher priority in 2009. With the arrival of the Emerging Risks Head of Unit and other staff in the 3rd and 4th quarter of 2008, priority was given to completing existing projects (emergency manual, ESCO Working Group). While new projects for data analysis were initiated in 2008, they will be finalized in 2009. Outsourcing of activities through contracts and grants was worth €3.3 m in 2008 vs. €1.3 m in 2007 for activity 2. To ease the travel burden on experts, more than 40% of meetings associated with this activity were held outside Parma.

To further enhance risk assessment methodologies, 17% of the Scientific Committee and Panel plenaries and 21% of their Working Groups were allocated to the development of documents such as the risk assessment of botanicals, recycling processes for plastics, source attribution for human cases of foodborne microbiological hazards, risk assessment of GM plants for food and feed, evaluation methods for pest risk assessments and technical guidance documents for preparation and presentation of feed additive applications. In addition, 12 public consultations for these documents and several stakeholder meetings were held to gain inputs from the Member States, international organizations and stakeholders. Two special Advisory Forum meetings were held, one for animal health and welfare and another for plant health, and it is intended that these will become annual events.

III.2 Scientific Committee

The Scientific Committee and several of its Working Groups contributed to the development, promotion and application of new and harmonised approaches and methodologies for risk assessment in the area of food and feed safety. In particular, a Guidance Document on transparency in risk assessments, specifically addressing the scientific aspects, was finalised and endorsed for public consultation by the Scientific Committee. Work was undertaken on the use of the benchmark dose approach, the implementation of EFSA's animal welfare policy in risk assessment processes, risk-benefit assessments of foods, the detection and evaluation of emerging risks, and the wider applicability of the threshold of toxicological concern concept in EFSA's risk assessments. The Scientific Committee Guidance Document on the safety assessment of botanicals and botanical preparations was tested on selected cases by an ESCO (EFSA Scientific Cooperation) Working Group. Another ESCO Working Group addressed the harmonisation of risk assessment approaches and made recommendations for further work within this area. A national expert meeting on aspartame is scheduled for April 2009.

III.3 Scientific Cooperation & Assistance

Assessment methodology

For this activity, AMU dedicated its resources to the provision of scientific support on risk assessment

methodology issues, data management and epidemiological and statistical analyses in the form of technical reports, presentations, Working Group participation or short-term consultations to Units and Panels and to the Scientific Committee and Advisory Forum (SC&AF) and the Management Team. Assistance was given to SC&AF on systematic literature review and to the Management Team on the organization and coordination of progress indicators, monthly scientific activity reporting, and coordination of the expert survey. AMU provided support for the development of workload tracking systems for several Panels and is responsible for the selection and the maintenance of the statistical and modelling software used in EFSA.

Since 2003 there have been reports in Europe and the USA of serious mortality of bees in beehives. In 2006 the term Colony Collapse Disorder (CCD) was first used to describe this phenomenon which is characterized by the rapid loss from a colony of its adult bee population. While the cause of CCD has not been determined, several aetiologies have been proposed. To begin to better understand this phenomenon, and upon request for collaboration from the French authorities (AFSSA), as a first step, AMU sent a questionnaire to the member states (through the EFSA Focal Point Network) to identify bee surveillance programmes and proceeded with reported the results of the data analysis. In order to investigate the phenomenon further, AMU launched a call for a project open to competent organizations under Article 36 of Regulation EC 178/2002. The outcome of the project will facilitate future EU level epidemiological research and surveillance programmes on CCD.

To prevent the introduction of plant pests into the European Union, plant epidemiological models are extremely valuable. Therefore, AMU launched a call under Article 36 of Regulation EC 178/2002 to establish an inventory of quantitative models describing the spread, establishment or development of plant pest on crops in Europe including geographical, climatic data and/or plant phenology as input factors. For this project, the focus is on model structure, parameters and data sets. This work will result in the creation of a structured, electronic inventory of the selected and analysed models and will be valuable for future plant pest predictive modelling work done by EFSA.

Data collection and exposure

An important component of any dietary exposure assessment is the amount of the respective food consumed. During the year, the Data Collection and Exposure (DATEX) Unit finalised the Concise European Food Consumption database. With assistance from an Article 36 project awarded to the German Federal Institute for Risk Assessment, consumption information at aggregated food group level from 19 countries was published on the EFSA website. Building on the cooperative efforts of the initial project, EFSA signed contracts with Member States for delivery of consumption data at the individual food level for adults and children. A total of 18 contracts were signed in 2008 for the intermediate comprehensive food consumption project.

A Working Group was formed to further harmonise collection of food consumption information in future studies to make European dietary information fully transparent. In addition, an Expert Group for Chemical Occurrence Data was established to cover the presence of harmful chemicals in food and feed. A Working Group on Left-censored data was established to evaluate the performance of a range of statistical approaches to deal with datasets on chemical contaminants in food and feeds in which a variable proportion of data are below the limit of detection.

A new record was set in response to the DATEX call for data on cadmium levels in food. Close to 140,000 analytical results were received from 20 Member States and industry covering the period 2003-2007. The highest cadmium concentrations were detected in fish and seafood, and in sugar and sugar products including chocolate. Specific food items that showed high concentrations were bivalve molluscs, fungi, oilseeds and edible offal. Although the fish and seafood group showed the highest mean concentration of cadmium, due to the higher volumes consumed, the highest contributors to average dietary exposure were cereals and cereal products, and vegetables, nuts and pulses. Adults with the highest dietary cadmium

intake included ovo-lacto-vegetarians who consume high amounts of nuts and oilseeds and frequent consumers of wild mushrooms or offal. The DATEX exposure assessment was used in developing the CONTAM Panel opinion on cadmium (see Activity 1).

Following an urgent request from the European Commission, the DATEX and CONTAM Units working in collaboration calculated within 3 working days a worst-case scenario for potential dietary intake of melamine in Europe. The European Commission also asked DATEX to identify whether the exposure of individuals to plant sterols would lead to intakes above the maximum suggested level of 3 g per day. DATEX found that regular consumers of these products constituted about 10-15% of the population. In general, there seemed to be little over-consumption, rather the average consumer exposure to plant sterols is on the low side of what is considered to be an effective dose. Following an urgent request from the Commission, DATEX contributed to the EFSA Statement on the public health risks of dioxins in pork from Ireland.

Emerging risks

The Emerging Risks Unit was established in 2008. The first scientific officer joined in February, the Head of Unit in mid-July and two other scientists in mid-November. Selection procedures for five other staff members were completed before the end of the year.

A paper describing the mission, mandate and activities of the Emerging Risks Unit was written. The Unit provided scientific and administrative support to the ESCO Working Group on Emerging Risks and 11 meetings were organised for its two subgroups. An interim report to the steering committee and a final report for the EFSA Executive Director were produced.

The EFSA *"Crisis Management Plan"* was revised, finalised and issued. Planning for a *"crisis handling exercise"* was initiated. Two calls for tender (*Development of a SAS Macro to import, analyse and visualize data from the DG-SANCO Rapid Alert System for Food and Feed Safety (RASFF) as a tool for early warning* under the Multiple Framework Contract for Assistance to the Assessment Methodology Unit for statistical analysis and ad hoc consultation upon request; and *Delivery of a database on bioactive constituents of food plants*) were launched, evaluated and signed. The Unit was established as the EFSA contact point for RASFF. Thus, the Unit supports access for EFSA staff to the RASFF database and has started development of regular statistical analysis and reporting of trends.

Several meetings with potential network partners and stakeholders within Europe and beyond (the European Commission, Member States, FAO, WHO, ECDC, EEA, SAFEFOODERA, GoGlobal etc.) were held. A total of 12 presentations were given at conferences, workshops and meetings of experts and decision makers. The Unit also contributed to EFSA's responses to the melamine contamination incident and the dioxin contamination of pork from Ireland and coordinated a report on "lessons learned".

Pesticide risk assessment peer review

In 2008, Regulation (EC) 396/2005 on MRLs (maximum residue levels) became fully applicable. In the framework of this Regulation, the Pesticide Risk Assessment Peer Review (PRAPeR) Unit completed the following activities:

- Developed procedures for the implementation of the Regulation;
- Delivered an assessment report in view of the inclusion of national MRLs for 107 active substances as temporary MRLs (Annex III to Regulation 396/2005);
- Drafted reasoned opinions on 15 active substances of concern following a request by the European Commission;
- Assessed applications for the setting of new MRLs, resulting in the adoption of 7 reasoned opinions in 2008;
- Launched an Article 36 project concerning the collection of Codex MRLs and related information;

- Started the review of all existing MRLs for active substances included in Annex I to Directive 91/414/EEC. PRAPeR organised a meeting with all Member States in order to explain the transmission of data necessary for this review.

In addition, PRAPeR started the drafting of the Annual Report on Pesticides Residues 2007, which will be issued for the first time by EFSA. In this context, PRAPeR organised a meeting on Future Data Collection of Pesticide Monitoring Data with all Member States.

Scientific cooperation

During 2008, the Focal Point network was established and by August all Focal Points agreements with the 27 Member States were signed (including financial support totalling €610,000 over 2007 and 2008). Focal Points support Advisory Forum Members and EFSA in exchanging information, maintaining the Article 36 network, populating the expert database, and raising EFSA's visibility. The Scientific Cooperation (SCO) Unit organised three Focal Point network meetings to discuss cooperation projects and participated in 14 national Focal Point kick-off meetings or similar events.

The system of cooperation through Article 36 was further developed. During 2008, the list of organisations designated by Member States to support EFSA in its tasks was updated with 10 new organisations from Romania and Bulgaria and amendments were made to the details of 11 existing organisations. Furthermore, the procedure to update the list of organisations in all Member States was launched in July and 134 valid nominations were received. From 2008, the Unit has coordinated the implementation of EFSA's Work Programme on grants and procurement, with a total budget of around €5.7 m.

The Expert Database, a database of scientific experts to support EFSA and Member States in finding suitable expertise for their scientific work, was launched in June. Currently around 500 experts from 40 countries are included and the number is increasing.

The Information Exchange Platform was launched in September for a 6-month pilot phase. The platform, located on the EFSA extranet, will facilitate the exchange and sharing of scientific information on risk assessment activities of interest to Member States and EFSA.

To increase the visibility of EFSA's scientific work and experts, a project was launched to develop the EFSA Journal into an online referenced journal. The Unit has also coordinated three special issues in peer reviewed scientific journals: *'The 2006 Bluetongue Outbreak in North-West Europe'*, *'Foot and Mouth Disease'* and *'EFSA's 5 Year Anniversary Scientific Forum'*. The Unit provided the scientific coordination for two Scientific Colloquia in 2008: on *Acrylamide Carcinogenicity* and *Campylobacter*. Each colloquium was attended by approximately 100 participants. In addition, two seminars, each attended by approximately 60 scientists, were organised to encourage leading scientists from new EU Member States to apply as members of EFSA's Scientific Panels.

The Unit supported two ESCO Working Groups, *Harmonisation of risk assessment methodologies* and *Risk and benefit of folic acid*.

Zoonoses

The main task of the Zoonoses Unit was to produce the annual Community Summary Report on Zoonoses and Zoonotic agents on the 2007 data. This report was prepared in close collaboration with the ECDC, which provided the data on the zoonoses cases in humans, and with EFSA's contractor in the Danish National Food Institute. All Member States provided their national datasets for the report and in addition 4 other European countries participated in the data collection. For the first time, a revised reporting system for foodborne outbreaks was applied in 2008 and, in total, 22 Member States sent information in this new format. Member State reporting was supported with a number of reporting manuals and the scientific and technical helpdesk run by the Unit. Moreover, the statistical analysis of trends over the years in Member States and at the Community level was improved. The report was finalised in December after consulting the

Member States and other stakeholders. In general, the report showed a stable situation or decreasing trends in the occurrence of zoonoses in the EU, with Salmonellosis and Campylobacteriosis remaining the most frequently reported zoonotic diseases.

The Unit also analysed two EU-wide baseline surveys on *Salmonella* in slaughter pigs and in turkeys. These results were published in four extensive reports where Member State data were first analysed descriptively and subsequently using statistical methods that revealed a number of risk factors related to *Salmonella* infections at the Community level. The prevalence of *Salmonella* in pigs and turkeys was found to vary significantly between Member States and, interestingly, the slaughterhouses were found to have an important effect on the *Salmonella* contamination of pig carcasses. In addition, on the request of the Commission, a new baseline survey protocol for *Salmonella* and *Campylobacter* in broiler meat was prepared by the Unit.

In-depth analyses of the national datasets on antimicrobial resistance and *Salmonella* serovars were started with contractors in the national institutes. The Unit also worked actively to further develop the analyses of the annual datasets on zoonoses, and Working Groups were established to consider optimal methods for statistical and spatial analyses of the data as well as to identify the fields in which to follow trends at the Community level.

The Unit continued its work on harmonisation of the monitoring and reporting of zoonoses across the Member States. Guidelines were issued for the reporting of antimicrobial resistance in commensal bacteria (*E. coli* and *Enterococci*) from animals and food, while ongoing work covered corresponding guidelines for verotoxigenic *E. coli*, *Listeria* and *Yersinia* in animals and food. In addition, the Unit collaborated with Member State institutes in the framework of the Article 36 grant projects on reporting and monitoring guidelines for rabies, Q fever and zoonotic parasites in animals as well as on conducting surveys of pathogenic microbes in food.

III.4 Risk Assessment

Food additives and nutrient sources added to food

The preparation of the revision of the Guidance Document on submissions for the evaluation of food additives was started with a procurement contract to develop the existing document.

Food contact materials, enzymes, flavourings and processing aids

An opinion on the evaluation of oxides materials used for removal of arsenic, manganese and iron from natural mineral water was adopted by the AFC Panel. The AFC Panel has also published guidelines on the evaluation of recycling processes for plastics for use in contact with food. Guidelines for the evaluation of active and intelligent packaging are being prepared by the CEF Panel and will be published in 2009. The CEF Panel is also preparing the dataset needed for evaluation of flavouring substances and enzymes. These Guidance Documents will be published in 2009.

Following a request from the European Commission to evaluate the safety of food irradiation an analysis of the literature is in preparation.

Animal health and welfare

In the framework of Article 36, the final reports on emerging animal diseases in the EU, including an update on vectors, classical swine fever (CSF), African horse sickness (AHS), African swine fever (ASF) and risk assessment guidelines for stunning and killing, were received. Four new calls for proposals were launched on emerging diseases in terrestrial and aquatic animals: (1) tuberculosis in wildlife; (2) Crimean Congo haemorrhagic fever and epizootic haemorrhagic disease; (3) aquatic diseases (viral haemorrhagic

septicaemia virus (VHSV) and Bonamia spp.); and (4) guidelines for animal welfare risk assessment of transport of animals. The AHAW Unit prepared two Article 36 calls to be launched in 2009 for animal welfare risk assessment guidelines on husbandry and management and the impact on animal health and welfare of genetic selection in livestock species.

The need for developing an electronic platform for communication between experts and AHAW staff has been identified and a specific IT tool (the AHAW extranet) is scheduled to become operational in mid-2009. AHAW attended meetings of the Standing Committee on the Food Chain and Animal Health, the CRL and other international meetings such as those of the OIE and has been invited to participate in several forums with stakeholders.

Biohazards

A self-tasking opinion on an overview of methods for source attribution for human cases of foodborne microbiological hazards was published. The use of the Qualified Presumption of Safety (QPS) approach to safety assessments of microorganisms intentionally added to feed and used in the production of additives for the feed and food chain was updated.

Feed additives

Following the entry into force of Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 (11 June 2008), EFSA developed a series of detailed technical Guidance Documents to assist applicants in the preparation and the presentation of their applications. Three stakeholder meetings were organised in 2008.

In the framework of Article 36, the final report on post-market monitoring of feed additives was received in July and accepted by EFSA. A new call for proposals was launched on 'Selected trace and ultratrace elements: biological role, content in feed and requirements in animal nutrition. Elements for risk assessment' and is currently in progress. In the framework of procurement, a call for proposals on 'pre-assessment of environmental impact of zinc and copper used in animal nutrition' was launched and is in progress.

In addition, as part of its self-tasking activities, the Panel prepared an opinion on the proposal to examine the scientific basis for the existing functional groups within the category of zootechnical additives (according to Annex I of Regulation (EC) No 1831/2003) in which it proposes the establishment of additional categories and functional groups, if necessary.

Genetically modified organisms

The GMO Panel adopted an updated draft Guidance Document for applicants concerning GMOs for food and feed, a draft report on the statistical analysis of data generated for the comparative food safety evaluation as well as a draft Guidance Document on the risk assessment of GM plants for non-food or non-feed purposes. For the latter two documents, public consultations were launched and adoption is scheduled for 2009.

The updated draft Guidance Document for applicants concerning GM plants for food and feed will be adopted by Member States as a Commission regulation. The GMO Panel and Unit provided technical support to the European Commission in discussions with the Standing Committee on the Food Chain and Animal Health as well as during a meeting with applicants.

Plant health

To support the provision of high-quality scientific advice, the following self-initiatives were implemented:

- Guidance Document for evaluating PRAs made by third parties to justify phytosanitary measures under Council Directive 2000/29/EC
- Official SLA agreement on collaboration with Agricast and the Joint Research Centre (JRC), Ispra on modelling used for predicting establishment and spread of harmful organisms

- Commencement of the Article 36 PRASSIS project, which aims to provide an inventory of data sources for phytosanitary pest risk assessment in the European Community

To establish the fundamentals for broadening the Panel activity in pest risk assessment and to assist Member States with PRAs, an Article 36 call was launched to develop a harmonised approach to the characterisation of risk in PRA. Also, development of a Guidance Document on a harmonised framework for the assessment of risks of organisms harmful to plants and plant products was initiated.

During 2008, there was regular communication with the Commission through the Standing Committee on Plant Health and the meetings of the Chief Officers for Plant Health were regularly attended with particular emphasis on the development of a harmonised framework for pest risk analysis in the EU. The first PLH Special Advisory Forum meeting was held in October 2008 and was attended by Forum members from 18 EU Member States and other national observers such as Norway and Switzerland.

Plant protection products and their residues

The number of Guidance Documents (GD) developed and updated by the PPR Panel (at the request of Member States) increased significantly. The Panel worked on the GD on persistence in soil and a Service Level Agreement with JRC was set up to provide support for this work. A public consultation on the two existing GDs on ecotoxicology (terrestrial and aquatic) was launched. For the GD on emissions from protected crop systems (e.g. greenhouses) a public consultation was carried out and some preparatory work outsourced. A collaborative project with EUROSTAT to collect data is in preparation.

For a GD on pesticide exposure assessment for workers, operators, bystanders and residents, a report generated via the Article 36 programme serves as a basis. The revision of the GD on dermal absorption also started with a public consultation. The preparatory work for the GD on the evaluation principles of the toxicological burden of metabolites, degradation and reaction products of pesticides in food commodities was outsourced through Article 36.

Work on the use of probabilistic methodology for dietary exposure assessment to pesticide residues was started. In relation to the GD on risk assessment for birds and mammals, a joint Working Group comprising EFSA, Member State representatives and the European Commission will consider the risk management issues and extract the final GD on the basis of the PPR scientific opinion. The PPR Unit collaborated with the OECD Pesticides programme (Environment, Health and Safety Division) in the preparation of GDs related to toxicology and residues.

Activity 2	Unit	2008 Budget	Staff	2008 Personnel Expenditure	2008 Infrastructure Expenditure	2008 Operational Expenditure	2008 Total Expenditure	%
Activity 2	Sci. Cooperation	1,8	10	0,8	0,4	0,5	1,7	96%
	Data collection	2,6	6	0,5	0,2	1,8	2,5	96%
	Emerging risks	1,0	6	0,5	0,2	0,2	0,9	96%
	Assessment methodology	1,1	8	0,6	0,3	0,1	1,1	97%
	Zoonoses	1,5	4	0,3	0,1	1,0	1,5	99%
	R.A. Units	5,2	20	1,6	0,7	2,7	5,1	98%
	Scientific Committee	1,2	5	0,4	0,2	0,5	1,1	94%
	Other	0,5	4	0,3	0,1	0,0	0,5	97%
TOTAL		14,8	63	5,1	2,3	6,9	14,3	97%

Table 2. Outputs in enhancing risk assessment methodologies in 2008 for Activity 2.

	AM U	DAT X	Em. Risk	SC O	Zoo n	PR APe R	SC	A F C	AH AW	AN S	BIO HAZ	C E F	CON TAM	FEE DA P	GM O	N D A	PP R	P L H	Tot al	Target 2008*
Guidanc e documen ts	0	0	0	0	6	0	2	1	0	0	0	2	0	16	1	0	0	1	29	23
Data collection reports	0	13	0	1	7	0	0	0	0	0	0	0	0	0	0	0	0	0	21	21
Other technical and scientific reports	15	4	2	26	4	23	3	0	0	0	2	0	0	0	0	0	0	0	79	28
Total	15	17	2	27	17	23	5	1	0	0	2	2	0	16	1	0	0	1	129	72
Contract s and grants	2	15	2	27	10	1	1	0	1	0	0	0	0	0	0	1	11	1	72	
Plenary/ Network meetings	0	2	2	3	5	2	5	2	0	0	0	1	0	1	0	0	5	0	28	
WG meetings	2	8	8	7	28	0	36	8	2	0	7	2	0	23	15	0	34	7	187	
Meetings with third parties	7	17	10	8	31	1	9	1	0	1	2	2	0	6	8	0	12	0	115	
Public consultati ons	0	0	0	0	0	0	1	1	0	0	0	0	0	0	3	0	6	1	12	
Presenta tions, lectures	20	18	12	100	20	0	6	1	1	0	1	5	1	5	4	0	7	1	202	
Papers in scientific literature	1	7	2	40	2	0	1	2	0	0	0	1	0	0	2	0	0	0	58	
Queries from other EFSA directorat es	4	8	0	12	13	0	6	5	0	0	8	5	0	29	8	0	3	0	101	
Other	12	6	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	22	

* Targets were reviewed in July 2008 in consultation with the European Commission. In addition the nomenclature for classification of EFSA outputs was formalised in 2008.

IV Communicate scientific advice and facilitate dialogue with interested parties (Activity 3)

IV.1 Communications overview

EFSA pursued the implementation of its communications activities guided by three overall objectives: coherence in its communications through strengthened cooperation with relevant authorities at national, European and international levels; simplicity and accessibility of its communications; and increased visibility and understanding of EFSA's scientific work.

Coherence

- Continued to work closely with Member States to develop communications networks and by cooperating inside and outside the Advisory Forum Communications Working Group (AFCWG) including joint communications activities. Coherence was strengthened through: pre-notification of major communications; proactive exchange throughout the development of communications on key issues such as animal cloning; building synergies and cross-linking between EFSA and Member State websites to strengthen understanding of the EU food safety system.
- Liaised closely with Member States and the European Commission on specific issues.
- Communicated fast-track assessments of such urgent issues as contaminated sunflower oil, melamine in Chinese milk products and dioxin contamination in Irish pork.
- Supported national food safety authorities by providing a complete web toolkit to Focal Points for their communications on the work of EFSA and the Advisory Forum; as a result, 18 Focal Points include a dedicated EFSA section.
- Shared best practices and skills with EU Member States. A standing item on the AFCWG agenda is the sharing of a case history, for instance in 2008 concerns in Austria about eating fruit from plants treated with antibiotics to protect against fire blight.
- Whilst information on consumer risk perception was shared between EFSA and Member States, the plan to work towards a common approach to monitoring and assessing public perception by means, for instance, of a Eurobarometer, will be carried out in 2009-2010.
- EFSA participated in the ECHA workshop on risk communications and participation in the EU agencies' information and communications network.
- Improved internal EFSA planning and processes to ensure integrated communications through, for example, the Communications Review Committee, based on activities flagged for communications in the EFSA monthly calendar of the status of its scientific activities.
- Updated guidelines on how staff and scientists should handle the media and set out a fresh plan on media training for EFSA senior staff and scientists.

Simplicity

- Presented EFSA's work online in simple terms including a graphical workflow of how EFSA develops opinions
- Improved accessibility and transparency by launching the online database of Annual Declarations of Interests of EFSA's scientific experts, and explaining the relevant policy behind it.
- Strengthened media relationships to increase and improve understanding of EFSA's work. This was also reinforced through a series of face-to-face meetings between invited journalists and EFSA's Executive Director.
- Used existing multimedia to increase uptake of live webcasting (Management Board in October attracted around 1,000 views) and advanced EFSA's online communications strategy by starting to procure future multimedia services.
- Organised events and provided targeted material about EFSA for regional and local audiences.

Visibility

- Proactively promoted EFSA in the media. Overall, EFSA-related media coverage increased by 62% in 2008 vs. 2007.
- Held press briefings on EFSA's scientific advice on nutrient profiles for products bearing nutritional and health claims and on EFSA's final opinion on animal cloning.
- Rolled-out new products to increase the reach of EFSA's work, such as three targeted quarterly newsletters, EFSA in focus (Food, Animals and Plants).
- Developed a harmonised look and feel for all communication products through the finalisation of EFSA's corporate identity guidelines.

- Increased outreach through many publications including the Annual Zoonoses report, three Scientific Colloquia summaries, 20 scientific posters, and five supplements in scientific journals.
- Continued to showcase EFSA's scientific work through its Scientific Colloquia, stands at international scientific conferences and joint EFSA-Member State events.
- Developed a communication campaign for EFSA's expert database (June) and the call to renew Scientific Committee and Panel members (October) throughout Member States.

Communications outputs

	2008	Increase compared with 2007
Web Visits	2.1 m	+43%
Highlights subscribers	21,140	+19%
Media coverage	11,652	+62%
Media queries	676	+59%
Press releases	30	+25%
Web News stories	39	No change
Interviews	123	+180%
Events	18	+29%
Publications	63	+9%

V.2 Cooperation with Member States: Advisory Forum

Five Advisory Forum meetings took place in 2008 to provide a platform for EFSA and the national authorities to exchange information and discuss priority issues regarding risk assessments and the scientific cooperation. In addition, two special Advisory Forum meetings on animal health and plant health, respectively, were organised. Two meetings of the Steering Group on Cooperation were held to overview the implementation of the scientific cooperation between Member States and EFSA. Finally, bilateral visits to several Member States took place.

IV.3 Relations with EU Institutions

European Commission

Following an initial meeting of the Executive Director with Commissioner for Health, Androulla Vassiliou, in April in Brussels, the Commissioner visited EFSA in Parma in July. The Commissioner met members of the Management Board, the Scientific Committee and senior EFSA staff for an exchange on priorities, Member State cooperation and EFSA working processes. The visit concluded with the Commissioner addressing all EFSA staff.

European Parliament

The Executive Director was invited to the ENVI Committee on two occasions and she also participated in two meetings organised by the Budgetary Control Committee on the discharge. In April 2008, a delegation of the European Parliament led by EFSA liaison MEP Kartika Liotard visited EFSA in Parma. The delegation consisting of MEPs and assistants, staff of the Secretariat and Political Groups met with the Chair of the Management Board, the Executive Director and EFSA Directors.

EFSA policy officers regularly monitored developments in the European Parliament mainly on the EU Animal Health Strategy, the White Paper on Nutrition and Obesity, the Food Improvement Package (additives, enzymes, flavourings and single authorization procedures), the Pesticides Package (sustainable use of pesticides and placing of plant protection products on the market) and budgetary matters (2008 discharge and 2009 budget). This involved participating in several EP Committee meetings including AGRI, BUDG and IMCO, while the focus remained on the ENVI Committee where EFSA is permanently represented.

Council of Ministers and Member States

Meetings of the Executive Director with the Slovenian Minister of Agriculture and the French Minister of Agriculture were organised in collaboration with the Slovenian and French Presidencies. EFSA participated in meetings (the Chief Veterinary Officers and the Chief Plant Protection Officers in Brussels) and conferences organized by the Slovenian Presidency. During the French Presidency, EFSA participated in an informal Agriculture Council meeting, seminars and conferences (on inspections in slaughterhouses, on rural development and pesticides) organized by the French Presidency, with a view *inter alia* to providing technical input to discussions on the regulatory framework of GMO's and to obtaining feedback on the draft Strategy Plan 2009-2013. EFSA also participated in the first joint CVO-COPHS meeting that was organized by the French Presidency and that discussed the Council position on EFSA's draft Strategic Plan 2009-2013. At the invitation of the EU Presidencies, EFSA's Management Board and Advisory Forum met in Ljubljana and Paris during the respective Presidency terms. In preparation for the next presidency, initial contacts have been established with the Permanent Representation of the Czech Republic and EFSA's Executive Director visited Prague in December.

The Director General, Health and Consumers and the Executive Director continued with their regular bilateral meetings (5 in 2008) and provided the basis for the permanent operational exchanges between EFSA and colleagues from the interface unit. An important step forward in the identification and management of joint priorities between DG Health and Consumers and EFSA was the development of a mutually agreed Roadmap on selected deadlines for mandates, which is regularly updated (every 3-4 months).

In addition to the continued facilitation of the involvement of Commission colleagues in scientific meetings at EFSA, the Advisory Forum and the Stakeholder Platform, senior representatives of EFSA participated in meetings of the European Commission's Advisory Group on the Food Chain, Animal Health and Plant Health as well as Standing Committees on a series of items under EFSA's remit, on invitation of the Commission Services. In November, EFSA and the Joint Research Centre (JRC) signed a Memorandum of Understanding for mutual cooperation.

Relations with EU Agencies

EFSA enhanced its relationships with other EU Agencies active in related fields by exchanging information and cooperating on matters of mutual interest. EFSA's Executive Director visited the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Chemical Agency (ECHA). In April, EFSA and the ECDC signed a Memorandum of Understanding to increase cooperation and exchange scientific information on topics of mutual interest including food safety, control of communicable diseases, infectious disease prevention and emergency responses. Additional meetings with these Agencies were organized by the Agencies' services throughout the year. EFSA is part of the Troika of Agencies network and will chair it in 2009.

In October, EFSA hosted and organized the 3rd European agencies meeting on network building, focusing on the Pre-Accession Programmes and the European Neighbourhood Policy (ENP). A total of 9 EU agencies participated in the meeting together with 2 representatives from the European Commission (DG Enlargement and DG RELEX).

Performance Indicators

- A mutually agreed Roadmap for internal management of deadlines and priorities was finalised between DG Health and Consumers and EFSA
- Number of written institutional questions from the EP dealt with by EFSA = 4
- Visit of the Environment Committee to EFSA = 1
- Executive Director appearances in the ENVI Committee = 2
- Meetings with EU presidencies and assistance provided for meetings = 8

IV.4 International Relations

Together with the FAO and the WHO, EFSA organized a conference on climate change and food safety held in the FAO premises in Rome in October. The conference involved speakers from all three organisations and DG Health and Consumers.

EFSA hosted several delegations of international partners to initiate and foster technical cooperation. These included the Minister of Food Safety from New Zealand, the Director of the US Centers of Epidemiology and Animal Welfare, the US Agriculture Attaché and Agriculture specialist from the US Embassy in Rome, the Director General of the Beijing Food Safety Administration, a delegation of representatives of the Mercosur Countries (Brazil, Argentina, Uruguay and Paraguay), a delegation of the Chinese Academy of Agricultural Sciences, the Chief Scientific Officer of the New Zealand Food Safety Authority and representatives of the Japanese Food Safety Commission. EFSA also hosted a TAIEX (the Technical Assistance and Information Exchange, an instrument of the Directorate-General Enlargement of the European Commission) study and hosted a visit of a Russian delegation on establishing pesticide maximum residue (MRL) levels. In addition, EFSA took part in the Commission delegation to the CODEX Task Force on Biotechnology in Japan. EFSA drafted a strategic approach to its International activities and it will be presented to Management Board in January 2009.

Pre-Accession Programme for Turkey, Croatia and Macedonia

Five training seminars were held in the Candidate countries, involving 179 experts from the three Candidate countries. They included contributions from EFSA staff, Panel members, members of EFSA Management Board and Advisory Forum, Member States, as well as from experts from Candidate countries. The latter took part in 23 EFSA meetings such as the Advisory Forum plenary meetings and Working Groups, EFSA networks and data collection Working Group meetings. In addition, a study tour for 12 experts from Turkey and Croatia to the UK Food Standards Agency and to the Department for Environment, Food and Rural Affairs was arranged. Plans for 2009 have been agreed by the EFSA Steering Committee. EFSA organised a meeting with other EU agencies involved in the pre-accession programme to share experiences and best practices.

Performance Indicators

- Meetings, conferences and training organised under the Pre-accession programme: 5 seminars with an average of 40 participants, 1 study tour and 18 EFSA meetings.
- Feedback and evaluation from meetings of pre-accession and neighbourhood meetings: 80% rated the meetings excellent/very good.

IV.5 Relations with stakeholders

Two plenary meetings of the Stakeholders Platform were organized in 2008, in Parma in April and in October in Brussels, to discuss topics such as health claims and future stakeholder policy. In the Brussels meeting, the Platform elected its new Chair, Dr. Andreas Varlamos, from BEUC. The new chair was invited to the December meeting of the Management Board as an observer. Dedicated technical meetings were organised on animal cloning and nanotechnology.

As a result of feedback from the Stakeholder Platform, a series of technical meetings were set up with stakeholders on sensitive topics, including: animal welfare aspects of farmed fish; assessment of silage additives; animal cloning; and nanotechnologies. The meetings were organized or hosted by EFSA, at a cost of about €50,000 in 2008 and they involved EFSA's Management Team, members of the Scientific Committee and other senior EFSA representatives.

In June, EFSA hosted the bi-annual meeting of the BEUC food officers of consumer organizations across Europe. The meeting was opened by a welcome speech by the Executive Director. In July, EFSA hosted a meeting with representatives of environmental non-governmental organisations (NGOs), specifically dedicated to discussing scientific and procedural issues related to the risk assessment of genetically modified organisms (GMOs).

Performance Indicators

- Number of Stakeholder Consultative Platform meetings = 2
- Number of consultations = 13

IV.6 Relations with Italy

The LPA Unit provided support for the interaction with the Italian local authorities on key settlement issues such as the European School, transport and the Final Seat. Additional advice and support was provided for the preparatory work for the roundtable organized in Rome in September between the Executive Director and the Undersecretary of State, and which also included the Minister of European Affairs and several Heads of Cabinets from the Ministries of Transport, Education, Foreign Affairs, Infrastructure and Health. Follow-up meetings were organised in November and December 2008. The Italian Minister for European Affairs, visited EFSA in late 2008 and his itinerary included the Scuola per l'Europa.

Activity 3	Unit	2008 Budget	Staff	2008 Personnel Expenditure	2008 Infrastructure Expenditure	2008 Operational Expenditure	2008 Total Expenditure	%
Activity 3	Advisory Forum	0,8	4	0,2	0,1	0,4	0,8	94%
	Legal & Policy	1,3	6	0,3	0,2	0,6	1,1	87%
	Press Office	1,5	13	0,7	0,4	0,3	1,5	98%
	Web	0,9	7	0,4	0,2	0,3	0,9	98%
	Publications & events	2,8	15	0,8	0,5	1,2	2,5	89%
	Other	0,9	5	0,3	0,2	0,4	0,9	99%
TOTAL		8,1	50	2,6	1,7	3,3	7,6	93%

V Manage and provide administrative support (Activity 4)

V.1 Overview

The overall aim of the Administration Directorate is to: provide efficient support to the Directorates of Risk Assessment, Scientific Cooperation & Assistance and Communications; improve EFSA's reporting and efficiency; promote a stimulating and rewarding working environment; and develop sound financial management.

V.2 Human Resource Policies

Time and workload monitoring was improved and a Flexi Time Policy was adopted on 1 April 2008. In addition, a Time Tracking application was introduced to enable EFSA management to estimate time spent on activities and hence cost. A HR Internal Administrative Guidance document on Time Tracking and Flexi Time was published on 1 May 2008.

During 2008 the following rules, guidance documents and policies were adopted:

- Requests for ergonomic equipment
- Guideline on retention of medical files
- Organisation of annual medical visits (revised version)
- Preventive medicine programme
- Learning and Training Policy and Training Plan for 2009
- Procedures for assistance through the Staff Regulations for staff with disabled children
- Flexitime Policy
- Internal Administrative Guidance on Time Tracking/Flexi time
- Internal Administrative Guidance on Overtime Procedures
- Internal Administrative Guidance on Sick leave
- Guideline on vaccinations required for mission
- Absences due to sickness or accidents
- Protecting the dignity of the person and preventing psychological and sexual harassment
- Establishment of a staff committee and election rules
- Rules on classification of staff

Regular reporting on these new rules and on the progress indicators were provided to Management Team and all staff.

V.3 Career Development

EFSA's Decision on Staff Appraisal was approved by the Commission in 2008, enabling the Authority to complete its first Career Development and Appraisal exercise. As a result, 17 staff members were reclassified/promoted to the next grade in their function group.

In relation to training, a budget of €400 k was spent, with more than two-thirds of the expenditure devoted to courses related to science, language training, EU affairs, communication and financial management courses. The average number of training days per staff member in 2008 was 8.4 days (based on 340 staff members).

Bi-monthly induction sessions with an enhanced content were organised in order to provide newcomers with a complete set of information. Job descriptions were monitored (98% of staff members have a job description) and progress was made to ensure the timely completion of probation period reports. The average number of probation reports received on time to August 2008 was 52% compared with 42% in 2007.

V.4 Recruitment

Recruitment of the Head of Human Resources (HR) was finalised and the appointee joined in September 2008. The HR team was reorganised to prioritise career development; recruitment had been previously prioritised due to the need to execute EFSA's Establishment Plan and hence the amount of resource required for recruitment will decrease from 2009 onwards.

In 2008, 45 Temporary Agents, 40 Contract Agents and 5 Seconded National Experts were recruited, meaning that EFSA's Recruitment Plan was executed up to 97% and its Establishment Plan up to 96%. Twelve trainees were selected and offered placements to carry out in-service training in order to acquire practical experience in the areas of science, communication or administration.

V.5 Working environment

Following the 2007 staff survey launched by the Staff Committee to identify key issues for its attention, working groups on Internal Communication and Facilities (working environment) were launched in

collaboration with the Staff Committee. Two actions plans were put in place in November 2008 in order to improve both areas and monitor progress.

A staff survey was launched in 2008 by EFSA Management to obtain feedback from staff on five specific aspects: Working environment, Organisation of work and staff relations, Satisfaction and career development, Information in EFSA, and EFSA and Parma. The results of the survey showed that the level of participation increased from 44% in 2007 to 55% in 2008, the average score for working environment, organisation of work and career satisfaction was 3.6/5.0 and that 87% of respondents were proud to work for EFSA.

Performance Indicators

Establishment Plan = 96% executed

Recruitment Plan = 97% executed

Number of staff reclassified/promoted = 17

Average number of training days per staff member = 8.4

Average number of days lost due to sick leave per staff member = 6

Staff turnover rate = 8%

V.6 Legal and Policy Affairs

The Legal and Policy Affairs Unit (LPA) was established in April 2008 combining staff with legal expertise from the former Legal and External Relations Units. The overall objectives of the new Unit are to strengthen the relationship with EU institutions, European and International partners and stakeholders and ensure the compliance of all EFSA operations with the legislation applicable to EFSA. A strategic approach to international activities was drafted in 2008 and will be presented to the Management Board in early 2009.

Legal support

The LPA Unit ensured legal support for all operations at EFSA. During 2008, legal support was particularly significant in the implementation of the EU Health and Nutrition Claims regulation and recent regulations impacting on the pesticides sector. The EFSA Policy on Declarations of Interests continued to be an item that required regulatory advice, both internally at EFSA and externally. In 2008 the Court of First Instance ruled inadmissible three actions brought against EFSA aiming at the annulment of scientific output of EFSA in the area of pesticides while a fourth applicant withdrew their application. Legal support was provided for monitoring regulatory and policy developments in the European Institutions, in particular the Food Improvement Package, Pesticides Package and Novel Food proposal. The Academy of European Law organised a conference on recent developments in EU Food Law which EFSA hosted at its premises.

Data protection

During 2008, the European Data Protection Supervisor (EDPS) issued two opinions in response to the EFSA Data Protection Officer's requests for prior checking: Career Development & Appraisal Cycle (28/01/2008) and EFSA's Experts Database (11/11/2008). Furthermore, as a result of consultation with the DPO, EDPS recommendations on the EFSA time tracking/flexitime system were implemented. Data controllers at EFSA made 7 notifications to the DPO on data processing operations in relation to the following topics: EFSA's Database on External Scientific Experts, Newsletter service, EFSA highlights, Registration for the PRAPeR MRL workspace on the EFSA extranet, Infobox-related activities, Information Exchange Platform, EFSA time tracking/flexitime system, and Anonymous staff surveys at EFSA.

Requests for access to documents

Given EFSA's emphasis on transparency and the provision of public information via its website, EFSA received few requests (16) for access to documents during 2008. All requests had positive outcomes and EFSA granted partial access to the requested documents in compliance with Regulation (EC) 1049/2001. Access requests were categorised as follows: one request in Nutrition & Health Claims, 11 requests in the

GMO area related to GMO applications under Regulation (EC) 1829/2003, one request in PRAPeR on napropamide, one request in FEEDAP on *Enterococcus faecium*, one in food additives on steviol glycosides, and one request for access to Advisory Forum meeting documents.

Performance Indicators

- Number of court cases lodged against EFSA = 3 cases ruled in favour of EFSA, one withdrawn
- Number of opinions of the EDPS on EFSA notifications = 2
- Number and outcome of access of documents requests = 16

V.7 Finance and Accounts

Finance

Budget Management and Activity-based budgeting (ABB)

EFSA's budget was built, managed and reported in line with its four core activities and budget execution was reported to the Management Team on a monthly basis. Comprehensive financial reports and dedicated financial and procurement training were made available online to the Financial & Procurement network. Grant committee meetings were held every month to monitor contracts and grants in the Risk Assessment and SCA Directorates. The appropriateness and efficiency of the human and financial resources were analysed by activity using the allocations of the various costs to Units and budget reallocations were implemented.

Financial Management

The volume of commitments and payments increased by 20% and 25%, respectively compared to 2007. Dedicated training was provided in order to improve the quality of the financial files submitted. Management of the centralised budget lines (mission, shuttle, flights, translation, catering, amounting to €5 million) was improved and workflows were updated and fully automated. Centralisation of the function of administration of meetings at EFSA, which represents a budget of €8.2 m, is under evaluation, aimed at enhancing efficiency.

Procurement and Grants

This activity was integrated into Finance following the establishment of LPA in April 2008. New guidance manuals, templates and training were provided to Units. The planning and monitoring of scientific outsourcing were reviewed. Approximately 60 new contracts and grants were signed in 2008 for the whole organisation.

Management Tools

A new release of the mission workflow application was launched and the ABB application for budget development was finalised – the latter process will be fully automated next year. Integration of various data sources for ABB reporting, i.e. financial systems, posting criteria and time tracking, is being finalised. The database for contracts, which facilitates financial management of the contracts and associated procurement procedures, was finalised. In line with the schedule of the European Commission, adoption of the accrual-based accounting (ABAC) system was postponed to early 2010. EFSA treasury and the requests for funds are established on the commitment execution and the ensuing cash flow estimates in order to limit the amount of cash available in EFSA bank accounts.

Internal Control Standards

The results of the Internal Control Standards self-assessment were presented to all Staff and an action plan developed and implemented to improve internal control effectiveness. A new structure for Internal Control Standards was adopted and a workshop aimed at identifying and addressing the main risks faced by EFSA was organised in December 2008.

Performance Indicators

- Budget execution rate increased from 91% in 2007 to an estimated 97% in 2008
- Payments were processed in compliance with the deadlines set by the Financial Regulation. In five cases however, interest on late payments were paid in view of the deadline for payment not having been met. In total, €1713 interest on late payment was paid.
- The preliminary findings of internal and external audits on procurement, contract and grant management in EFSA show an overall improvement and better planning of these activities
- The internal Audit report on grant management and carry-forward processes confirmed the action already taken in order to strengthen the verification of carry-forward and establish differentiated credits
- No critical comments were received from internal and external audits on procurement procedures, contract and grant management in EFSA
- The transaction volumes (+36 % in commitments and + 21 % in payments) were accompanied by economies of scale in terms of processing
- A new mission workflow was put in production. The centralisation and automation process for the organisation of meetings was not put in motion in 2008

Accounts

The number of transactions executed and payments volume increased by 10% and 25%, respectively in 2008 compared with 2007. The average execution time was 2.1 days for payments (target was 3 days or less). The increase was also reflected in the management of the new legal entity files and bank account files for suppliers and experts. EFSA has now more than 6,200 records in its third party (bank accounts) central database. Migration to ABAC is now scheduled for 2010. An external audit was launched in November 2008 to assess the security of the Accounting and Financial IT system.

V.8 Information Technology & Operations

Infrastructure & Support Team

Delivery of standard user equipment to all new staff

Standard user equipment (PC, laptop, monitor, PDA and IP phone) was monitored carefully and equipment was delivered on the day of arrival to 143 newcomers.

Implementation of the security and reliability plan

The plan for security and reliability improvements, incorporating monitoring, redundancy, outsourcing of key infrastructure components and improvement of conference room IT facilities, was implemented with the exception of the outsourcing element. The latter will be discussed in the context of the IT strategy of the incoming Head of IT & Operations in 2009.

Equipment of the "crisis room" finalized during the first quarter of 2008

The "crisis room" project was completed in May 2008 (scheduled for the first quarter of 2008). The crisis room is fully operational and it also provides video-conferencing facilities. Test sessions were completed as follows:

- ⇒ June 9, test with Slovak Republic
- ⇒ 18 September, test with 10 simultaneous attendees (German, Austria, Italy, Hungary, Greece, Ireland, Sweden, Poland United Kingdom and DG Health and Consumers)
- ⇒ 30 September, test with Belgium
- ⇒ 30 October, test with DG Health and Consumers

Efficient management of meeting rooms

Inside the General Services team a specific office, dealing exclusively with meeting rooms' issues (reconfiguration, booking, cleaning and technical improvement), was established. Users now have a unique access point dealing with all issues related to the management of meeting rooms. EFSA organized 452 meetings with external parties in its meeting rooms in 2008.

IT Service Level Agreements

The service level agreements (SLAs) for equipment requests, response to user calls and key systems uptime have not been established. However, a number of preliminary actions have been taken in advance of their establishment in 2009. Monitoring software has been installed to measure key systems uptime which will define future SLAs.

Final Seat Project

Several meetings at different levels (technical and financial) were held. The definitive project was approved by EFSA and the Comune di Parma in April 2008. The executive project was approved in November 2008 and the STU Authority launched the tender to select the builder in November 2008.

Health & Safety

A Health and Safety Committee was established and is scheduled to meet four times per annum. An action plan was drafted and monitored on a regular basis by the members of the committee. The major activities undertaken were: risk assessment of each room; finalization of two contracts related to health and safety; fire warden and first aid training; creation of an evacuation plan; organisation of two evacuation drills; installation of polarized table lamps; and setting up a relaxation room.

Performance Indicators

- Final Seat project: Open Call for Tender to select the Builder launched on 20 November 2008 by STU Authority (Comune di Parma)
- Workspaces provided for all newcomers, interims and trainees in the current buildings without additional office spaces
- Improved working conditions: 150 polarized table lamps and 50 halogen lamps installed
- Crisis room delivered in the first quarter of 2008
- Standard user equipment delivered to all the new staff (143) on the day of arrival

Application Development Team

Support for strategic planning

Support for strategic planning was provided by defining and maintaining a 3-year rolling plan for IT projects, based on the collection and analysis of user needs from user surveys. All six IT Project Managers and the Team Leader contributed to this process. The move to ABAC has been delayed in agreement with DG Budget.

The development of new functionalities in the IT Tool to implement ABB is ongoing at a cost of €36,000 for consultancy. The first two functionalities of the Document Register (Chrono-In, Circulation Sheet) were completed at a cost of €123,000 for consultancy. A first prototype of the new Intranet is being carried out at a cost of €41,400 for consultancy. The automation of the Web Publishing process was improved at a cost of €167,000 for software licenses, hardware resources and consultancy. Three other processes were re-engineered: Time Tracking (€75,000); Declarations of Interest (€183,000); and the database of experts (€82,500).

Data collection and reports framework

Delivery of the Data Collection Framework was achieved at a cost of €52,500. Three data collections were supported: Zoonoses (€270,000); the first version of the Comprehensive Food Consumption database (€42,400); and the first version of MOPeR (€14,700). Two Community Reports were supported: Zoonoses and MOPeR.

Delivery of website, extranet and Register of Questions

The functionality of the EFSA website was improved at a cost of €170,000 for software licenses and maintenance, hardware resources and consultancy. Likewise, the Extranet platform was enhanced at a cost of €172,000 for software licences and maintenance, hardware resources and consultancy. New specific features included: enhancement of the Advisory Forum community at a cost of €26,000 for consultancy; a new Contacts Database (€22,000); and an enhanced GMO community (€45,000). The new version of the Register of Question, improved automatic calculation of progress indicators, was delivered at a cost of €220,000.

Support for emerging risk identification

The required support for Emerging Risk Identification was provided at a cost of €19,800.

Attainment of CMMI (Capability Maturity Model Integration) level 3

CMM-I level 3 was obtained with the support of all the staff of the Application Development Unit. This function involved all the staff of the Application Development team at 10% of their time.

Performance Indicators

- Implemented 7 major projects for automation of administrative tasks
- Delivered the data collection framework, supported three data collections and two Community Reports
- Delivered EFSA website, extranet and a new Register of Questions
- Supported emerging risk identification
- Attained CMMI (Capability Maturity Model Integration) level 3 accreditation

V.9 Quality Management

A Quality Policy was implemented highlighting EFSA's Quality Statement, the scope, objectives, activities and guiding principles of the Quality Management System and its implementation. In order to document the Quality Management System, high level risk areas were identified in EFSA's scientific workflows and Standard Operating Procedures developed. In addition, EFSA's self- and internal-review was launched and the external review is scheduled for implementation in 2009.

Activity 4	Unit	2008 Budget	Staff	2008 Personnel Expenditure	2008 Infrastructure Expenditure	2008 Operational Expenditure	2008 Total Expenditure	%
Activity 4	Human Resources	2,4	21	1,7	0,7	0,0	2,4	99%
	IT & Operations	3,6	31	2,5	1,0	0,0	3,5	99%
	Finance	2,4	21	1,7	0,7	0,0	2,4	99%
	Legal & Policy	0,6	5	0,4	0,2	0,0	0,6	99%
	Account	0,5	4	0,3	0,1	0,0	0,5	99%
	Library	0,6	5	0,4	0,2	0,0	0,6	99%
	Other Operational	1,1	10	0,8	0,3	0,0	1,1	99%
	TOTAL	11,1	97	7,9	3,1	0,0	11,0	99%

Annex 1: Budget Execution 2008

1. 2008 Budget execution

- 1 EUR 64.2 million or **97%** of the EUR 66.4 million budget (including the Pre-accession program) was committed.
- 2 This result was achieved in spite of delays in recruitment (the last recruits completing the establishment plan will join either in January or February this year). The corresponding financial resources available were transferred to Infrastructure and Information Technology projects.
- 3 EUR 48.7 million or **73%** of the total appropriations were paid. This payment level stands below the forecast made at the beginning of the year (EUR 53.4 million) as major subcontracting scientific or IT projects have started during the last quarter of 2008.

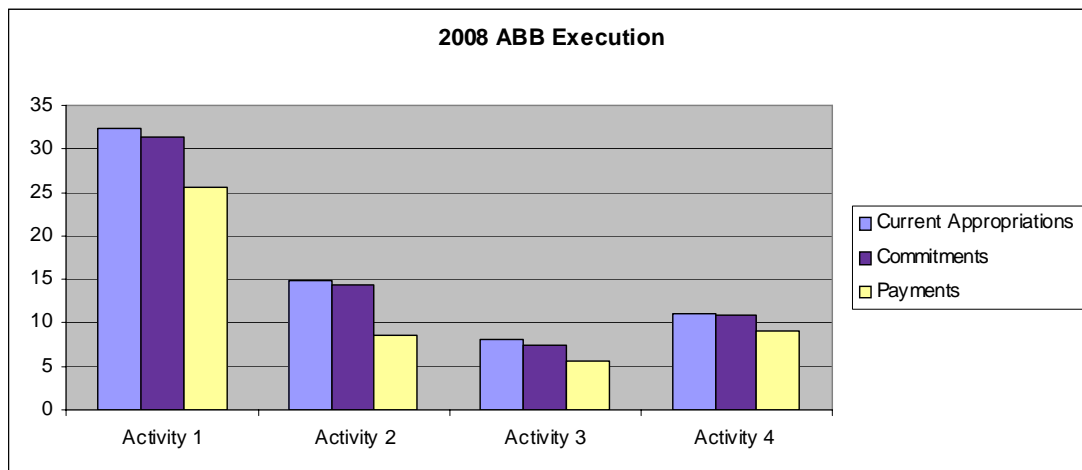
The following table and chart represent the budget execution along with the four activities identified by EFSA (Activity Based Budgeting) :

- Activity 1: Provide scientific opinion and advice to the European Commission, the European Parliament and the Member States
- Activity 2: Enhance risk assessment methodologies in Europe
- Activity 3: Communicate scientific advice and dialogue with interested parties
- Activity 4: Manage and provide administrative support

Activity (in MEUR)	Initial Appropriations	Current Appropriations	Commitments	% Committed*	Payments	% Paid*
Activity 1	32,7	32,3	31,3	97%	25,4	78%
Activity 2	13,5	14,8	14,3	97%	8,7	59%
Activity 3	9,5	8,1	7,6	92%	5,5	68%
Activity 4	10,7	11,1	11,0	99%	9,1	82%
TOTAL	66,4	66,4	64,2	97%	48,7	73%

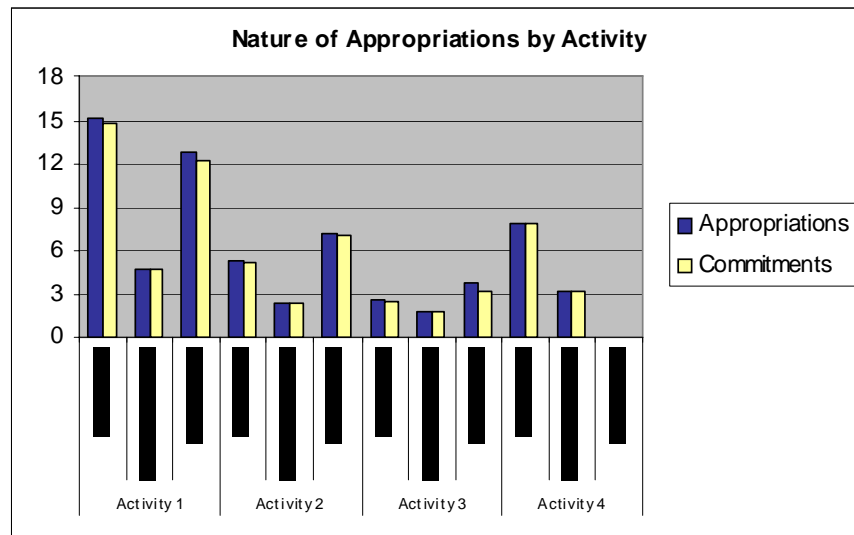
*committed or paid versus current appropriations

The detailed execution by activity is as follow:



Activity	Titles	Initial Appropriations	Current Appropriations	%	Commitments 2008 M€	%
	PERSONNEL	16.2	15,1	23%	14,7	97%
	INFRASTRUCTURE	3.4	4,6	7%	4,6	100%
	OPERATIONS	13.1	12,7	19%	12,0	95%
A1 Scientific opinions & advices		32,7	32,3	49%	31.3	97%
	PERSONNEL	5.7	5,3	8%	5,1	96%
	INFRASTRUCTURE	1.6	2,3	3%	2,3	100%
	OPERATIONS	6.2	7,2	11%	6,9	96%
A2 Methodologies & scientific cooperation		13.5	14,8	22%	14.3	97%
	PERSONNEL	3.9	2,6	4%	2,6	97%
	INFRASTRUCTURE	1.4	1,7	3%	1,7	100%
	OPERATIONS	4.2	3,7	6%	3,3	87%
A3 Risk communication & relationships		9.5	8,1	12%	7.6	93%
	PERSONNEL	8.3	7,9	12%	7,9	99%
	INFRASTRUCTURE	2.4	3,2	5%	3,1	97%
	OPERATIONS	0,0	0,0	0%	0,0	0%
A4 Administration		10.7	11,1	17%	11.0	99%
GRAND TOTAL		66,4	66,4	100%	64,2	97%

Whereas the level of commitment for the operational activities in Science reached 97 % at year-end, the execution of the operational activities reached a similar level indicating a high operational execution. The Communication activities achieved a 93% budget execution mainly due to the postponement of the evaluation project (Eurobarometer). The Administration support reached 99% budget execution. The level of the execution for personnel and infrastructure expenditures mirror, for all activities, the level of recruitment in the different activities.



2. Comparison to 2007

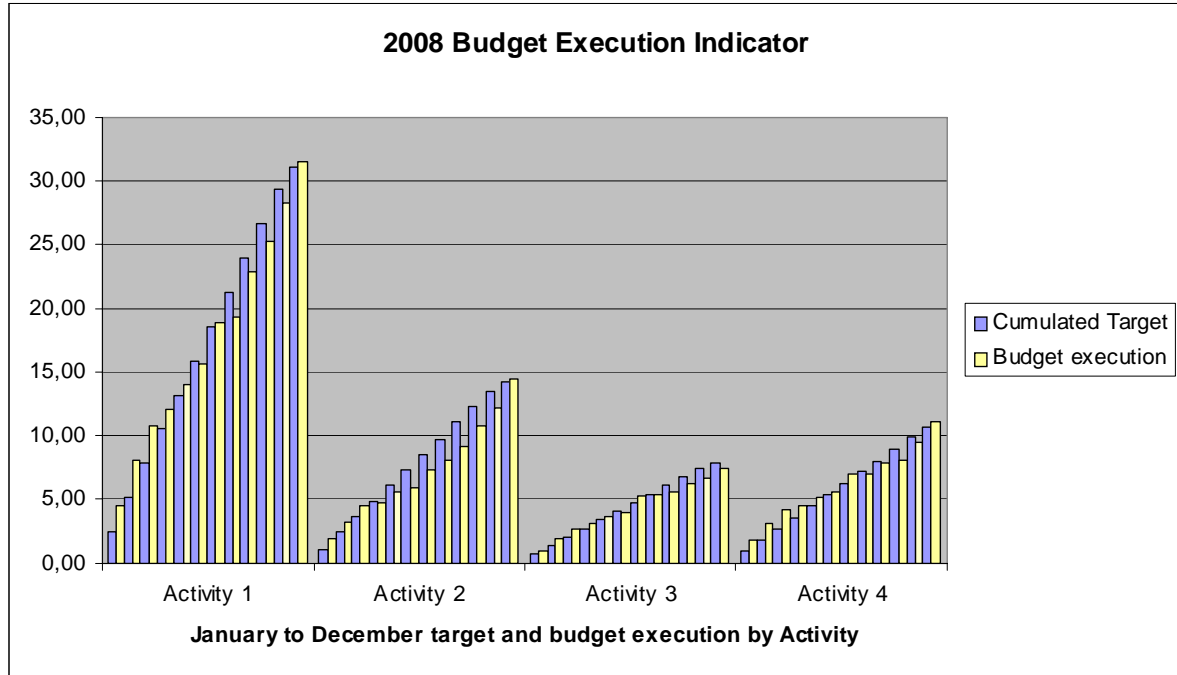
Compared to last year, the budget execution increased by EUR 16.8 million and the payments by EUR 9.9 million or an increase of respectively 36% and 26%. Activities 1 and 2 generated the bulk of the increase (+ EUR 14.9 million) while the communication activities remain at the same level compared to last year. In particular, Activity 2 has increased by 70% as compared to last year, the Directorate of Scientific Cooperation and Assistance having been significantly developed. In particular, scientific grants and procurement have been developed (as detailed in the table below). Administration activities increased by 24 % as important IT and infrastructure projects have been initiated.

EUR million	Execution 2008	Execution 2007	Increase	Payments 2008	Payments 2007	Increase
1- Provide Scientific Advice & Opinion	31,4	22,4	40%	25,5	18,8	35%
2- Risk assessment methodologies	14,4	8,5	70%	8,7	6,6	32%
3- Communication and dialogue	7,5	7,7	-2%	5,5	5,5	-1%
4- Management and Administration	11,0	8,9	24%	9,1	7,8	16%
TOTAL	64,2	47,4	36%	48,7	38,8	26%

EUR million	Appropriations 2008	Executed 2008	Executed 2007
Science meetings	9.0	8.3	6.6
Science contracts	3.7	3.6	1.1
Science grants	3.2	3.2	1.7
TOTAL	15.9	15.3	9.4

3. Budget Execution Indicator

The final 97 % execution rate stands 1 % above the 96 % execution forecast set at the beginning of 2008. On a monthly basis, the execution of the four activities is as follows:

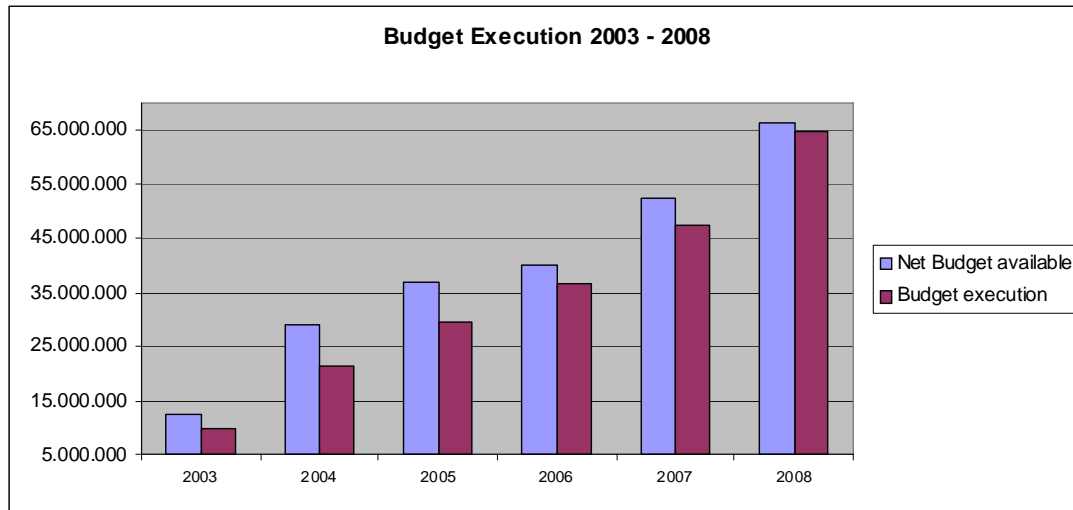


On a monthly basis, the scientific activities report the same pattern i.e., slightly above target during the first quarter, then the budget execution went below target due to delays in the finalisation of the grant and contracts agreements. When finalised, these agreements brought these activities slightly over the year-end target. The communication activities were on target until September. However, the postponement of the evaluation project (Eurobarometer), had a negative impact on the budget execution and the year-end target was not reached. Administration, with 99 %, was close to full execution and above the target set at the beginning of the year.

4. Budget Execution over years

Year	Budget available	Global transfer / Reserve	Net Budget available	Budget execution	Execution rate before transfer / Reserve	Execution rate after transfer / Reserve
2003	12.6	-	12.6	9.9	79%	79%
2004	29.1	-	29.1	21.3	73%	73%
2005	36.9	-	36.9	29.8	81%	81%
2006	47.1	-6.9	40.2	36.4	77%	90%
2007	61.7	-9.5	52.2	47.4	77%	91%
2008	66.4	-	66.4	64.2	97%	97%

The budget execution since 2003 increased from EUR 9.9 million to EUR 64.2 million or a yearly 40 % increase over the period. It is also worth noting that the execution rate has noticeably improved to reach 97 % in 2008.



5. Detailed Budget Execution

Chapter		Budget Appropriation	Executed Commitment	% Committed	Payment Appropriation	Executed Payment	% Paid	RAL (2)-(4)
1100	Basic salary	16.697.000,00	16.671.080,71	99,84 %	16.697.000,00	16.671.080,71	99,84 %	0,00
1101	Family allowance	1.587.500,00	1.570.576,11	98,93 %	1.587.500,00	1.570.576,11	98,93 %	0,00
1102	Transfer and expatriation allowance	2.179.000,00	2.174.593,62	99,80 %	2.179.000,00	2.174.593,62	99,80 %	0,00
1103	Secretarial allowance	21.000,00	18.171,49	86,53 %	21.000,00	18.171,49	86,53 %	0,00
1113	Stagiaires	90.000,00	54.319,10	60,35 %	90.000,00	52.802,63	58,67 %	1.516,47
1115	Contract staff	1.900.000,00	1.897.594,53	99,87 %	1.900.000,00	1.897.594,53	99,87 %	0,00
1130	Insurance against sickness	580.000,00	568.986,76	98,10 %	580.000,00	568.986,76	98,10 %	0,00
1131	Insurance against accidents and occupational disease	126.000,00	118.566,26	94,10 %	126.000,00	118.566,26	94,10 %	0,00
1132	Unemployment insurance for temporary staff	222.000,00	203.545,82	91,69 %	222.000,00	203.545,82	91,69 %	0,00
1140	Birth and death allowance	12.000,00	2.776,34	23,14 %	12.000,00	2.776,34	23,14 %	0,00
1141	Annual leave travelling expenses	394.000,00	393.112,18	99,77 %	394.000,00	393.112,18	99,77 %	0,00
1147	Call on duties	25.000,00	20.050,98	80,20 %	25.000,00	20.050,98	80,20 %	0,00
1150	Overtime	5.000,00	0	0 %	5.000,00	0	0 %	0
1170	Freelance and joint interpreting and conference service interpreters	2.000,00	0,00	0,00 %	2.000,00	0	0 %	0,00
1171	Translation centre Luxembourg (administrative matters)	143.000,00	143.000,00	100,00 %	143.000,00	121.779,04	85,16 %	21.220,96
1172	Payment for administrative assistance from the Community institutions	230.000,00	171.127,79	74,40 %	230.000,00	160.152,20	69,63 %	10.975,59
1175	Interim services	713.000,00	696.523,53	97,69 %	713.000,00	517.198,42	72,54 %	179.325,11

mb 29 01 09 item 6 doc 4 - Annual Activity Report 2008 - adopted

1176	Consultancy	25.000,00	4.700,00	18,80 %	25.000,00	0,00	0,00 %	4.700,00
1177	Other services	215.000,00	208.987,74	97,20 %	215.000,00	69.747,74	32,44 %	139.240,00
1180	Miscellaneous expenditure on recruitment	485.000,00	479.706,60	98,91 %	485.000,00	235.100,34	48,47 %	244.606,26
1181	Travel expenses (including for members of the family)	21.000,00	18.441,43	87,82 %	21.000,00	18.441,43	87,82 %	0,00
1182	Installation, resettlement and transfer allowances	482.000,00	457.896,99	95,00 %	482.000,00	457.896,99	95,00 %	0,00
1183	Removal expenses	295.000,00	295.000,00	100,00 %	295.000,00	199.018,27	67,46 %	95.981,73
1184	Temporary daily subsistence allowance	293.000,00	280.932,32	95,88 %	293.000,00	280.932,32	95,88 %	0,00
1190	WEIGHTINGS	2.056.240,00	2.050.831,52	99,74 %	2.056.240,00	2.050.831,52	99,74 %	0,00
Chapter 11		28.798.740,00	28.500.521,82	98,96 %	28.798.740,00	27.802.955,70	96,54 %	697.566,12
1300	Mission and travel expenses	465.000,00	425.532,47	91,51 %	465.000,00	278.489,51	59,89 %	147.042,96
1301	Shuttles for missions and duty	74.000,00	74.000,00	100,00 %	74.000,00	53.900,80	72,84 %	20.099,20
Chapter 13		539.000,00	499.532,47	92,68 %	539.000,00	332.390,31	61,67 %	167.142,16
1400	Restaurants, meals and canteens	45.000,00	41.302,00	91,78 %	45.000,00	34.747,90	77,22 %	6.554,10
1410	Medical service	172.000,00	123.198,80	71,63 %	172.000,00	47.746,39	27,76 %	75.452,41
1420	Further training, language courses and retraining for staff	480.000,00	410.142,11	85,45 %	480.000,00	144.004,25	30,00 %	266.137,86
Chapter 14		697.000,00	574.642,91	82,45 %	697.000,00	226.498,54	32,50 %	348.144,37
1520	Visiting experts, National Experts on Detachment	549.000,00	489.123,65	89,09 %	549.000,00	463.061,83	84,35 %	26.061,82
Chapter 15		549.000,00	489.123,65	89,09 %	549.000,00	463.061,83	84,35 %	26.061,82
1610	Social contacts between staff	115.000,00	67.333,14	58,55 %	115.000,00	32.697,97	28,43 %	34.635,17
1620	Other interventions	30.000,00	4.136,00	13,79 %	30.000,00	4.136,00	13,79 %	0,00
1630	Early childhood centres and other creches	80.000,00	46.749,00	58,44 %	80.000,00	33.410,28	41,76 %	13.338,72
Chapter 16		225.000,00	118.218,14	52,54 %	225.000,00	70.244,25	31,22 %	47.973,89
1700	Reception and entertainment expenses	100.000,00	50.616,62	50,62 %	100.000,00	31.684,43	31,68 %	18.932,19
Chapter 17		100.000,00	50.616,62	50,62 %	100.000,00	31.684,43	31,68 %	18.932,19
Title 1		30.908.740,00	30.232.655,61	97,81 %	30.908.740,00	28.926.835,06	93,59 %	1.305.820,55
2000	Rent	2.356.850,00	2.356.718,24	99,99 %	2.356.850,00	2.343.217,91	99,42 %	13.500,33
2010	Insurance	32.500,00	32.500,00	100,00 %	32.500,00	32.500,00	100,00 %	0,00
2020	Water, gas, electricity and heating	411.000,00	411.000,00	100,00 %	411.000,00	288.329,10	70,15 %	122.670,90
2030	Maintenance	192.000,00	191.985,40	99,99 %	192.000,00	82.677,82	43,06 %	109.307,58
2031	Cleaning	191.000,00	190.992,38	100,00 %	191.000,00	142.365,01	74,54 %	48.627,37
2040	Refurbishment of premises/ Fitting out	625.000,00	624.650,62	99,94 %	625.000,00	104.511,78	16,72 %	520.138,84
2050	Security and surveillance of buildings	684.200,00	684.200,00	100,00 %	684.200,00	436.191,76	63,75 %	248.008,24
2080	preliminary to construction, acquisition or rental of immovable property	2.000,00	1.733,33	86,67 %	2.000,00	1.733,33	86,67 %	0,00
2090	Other expenditure on buildings	78.450,00	78.450,00	100,00 %	78.450,00	72.998,96	93,05 %	5.451,04
Chapter 20		4.573.000,00	4.572.229,97	99,98 %	4.573.000,00	3.504.525,67	76,64 %	1.067.704,30

mb 29 01 09 item 6 doc 4 - Annual Activity Report 2008 - adopted

2100	Purchase/ Maintenance of equipment	1.033.760,00	1.013.406,65	98,03 %	1.033.760,00	531.826,01	51,45 %	481.580,64
2101	Purchase / maintenance of software	827.100,00	824.520,28	99,69 %	827.100,00	460.210,47	55,64 %	364.309,81
2103	Software development	2.970.000,00	2.969.299,34	99,98 %	2.970.000,00	1.018.356,34	34,29 %	1.950.943,00
2104	User Support	614.000,00	613.874,00	99,98 %	614.000,00	317.000,00	51,63 %	296.874,00
Chapter 21		5.444.860,00	5.421.100,27	99,56 %	5.444.860,00	2.327.392,82	42,74 %	3.093.707,45
2200	Technical equipment and installations	304.500,00	303.712,89	99,74 %	304.500,00	131.781,54	43,28 %	171.931,35
2201	Hire or leasing of technical equipment and installations	3.000,00	3.000,00	100,00 %	3.000,00	0	0 %	3.000,00
2202	Maintenance and repair of technical equipment and installations	5.000,00	5.000,00	100,00 %	5.000,00	1.162,91	23,26 %	3.837,09
2210	Purchase of furniture	45.000,00	45.000,00	100,00 %	45.000,00	37.335,43	82,97 %	7.664,57
2250	Library stocks, purchase and preservation of books	9.000,00	8.157,16	90,64 %	9.000,00	6.810,26	75,67 %	1.346,90
2251	Special library, documentation and reproduction equipment	6.500,00	6.314,50	97,15 %	6.500,00	5.619,50	86,45 %	695,00
2255	Subscriptions and purchase of information media	10.000,00	9.240,28	92,40 %	10.000,00	8.740,28	87,40 %	500,00
Chapter 22		383.000,00	380.424,83	99,33 %	383.000,00	191.449,92	49,99 %	188.974,91
2300	Stationery and office supplies	179.000,00	178.998,00	100,00 %	179.000,00	137.424,70	76,77 %	41.573,30
2320	Bank charges	4.000,00	102,81	2,57 %	4.000,00	102,81	2,57 %	0,00
2330	Legal expenses	66.000,00	63.692,99	96,50 %	66.000,00	63.692,99	96,50 %	0,00
2350	Miscellaneous insurance	24.500,00	24.500,00	100,00 %	24.500,00	2.276,00	9,29 %	22.224,00
2353	Removals and associated handling	18.000,00	18.000,00	100,00 %	18.000,00	12.649,57	70,28 %	5.350,43
2390	Publications	32.400,00	8.838,36	27,28 %	32.400,00	6.944,06	21,43 %	1.894,30
Chapter 23		323.900,00	294.132,16	90,81 %	323.900,00	223.090,13	68,88 %	71.042,03
2400	Postal charges	72.000,00	67.358,00	93,55 %	72.000,00	54.539,43	75,75 %	12.818,57
2410	Telecommunications subscriptions and charges	250.300,00	248.689,20	99,36 %	250.300,00	140.333,73	56,07 %	108.355,47
2411	Purchase and installation of equipment	450.200,00	449.663,96	99,88 %	450.200,00	235.571,51	52,33 %	214.092,45
Chapter 24		772.500,00	765.711,16	99,12 %	772.500,00	430.444,67	55,72 %	335.266,49
2500	Management Board meetings	390.000,00	343.432,99	88,06 %	390.000,00	233.795,65	59,95 %	109.637,34
Chapter 25		390.000,00	343.432,99	88,06 %	390.000,00	233.795,65	59,95 %	109.637,34
Title 2		11.887.260,00	11.777.031,38	99,07 %	11.887.260,00	6.910.698,86	58,14 %	4.866.332,52
3000	ANS: Scientific co-operation with external experts	225.000,00	221.000,00	98,22 %	225.000,00	164.900,00	73,29 %	56.100,00
3002	ANS: Travel/subsistence and indemnities expenses for members of the Panel and its Working Groups	205.000,00	176.115,93	85,91 %	205.000,00	148.479,62	72,43 %	27.636,31
3010	CEF: Scientific co-operation with external experts	290.000,00	264.071,00	91,06 %	290.000,00	65.557,00	22,61 %	198.514,00
3012	CEF: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	728.000,00	676.329,44	92,90 %	728.000,00	594.863,84	81,71 %	81.465,60
3020	FEEDAP: Scientific co-operation with external experts	49.000,00	48.208,00	98,38 %	49.000,00	14.462,00	29,51 %	33.746,00
3021	FEEDAP: Subventions for studies and evaluations	103.500,00	103.499,92	100,00 %	103.500,00	23.374,98	22,58 %	80.124,94
3022	FEEDAP: travel / subsistence and indemnities expenses for members of the Panel and its working Groups	724.500,00	719.965,82	99,37 %	724.500,00	680.331,77	93,90 %	39.634,05

mb 29 01 09 item 6 doc 4 - Annual Activity Report 2008 - adopted

3030	PLH: Scientific co-operation with external experts	200.000,00	200.000,00	100,00 %	200.000,00	0	0 %	200.000,00
3031	PLH: Subventions for studies and evaluations	100.000,00	100.000,00	100,00 %	100.000,00	20.000,00	20,00 %	80.000,00
3032	PLH: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	478.000,00	456.245,62	95,45 %	478.000,00	427.550,94	89,45 %	28.694,68
3040	PPR: Scientific co-operation with external experts	345.000,00	344.825,00	99,95 %	345.000,00	7.213,00	2,09 %	337.612,00
3041	PPR: Subventions for studies and evaluations	135.000,00	131.346,84	97,29 %	135.000,00	17.086,71	12,66 %	114.260,13
3042	PPR: Travel / subsistence and indemnities expenses for members of the Panel and its Working Group	436.000,00	396.965,48	91,05 %	436.000,00	378.714,43	86,86 %	18.251,05
3052	GMO: Travel / subsistence and indemnities expenses for members of the Panel and its working Groups	775.000,00	736.455,58	95,03 %	775.000,00	690.130,49	89,05 %	46.325,09
3060	NDA: Scientific co-operation with external experts	4.000,00	3.500,00	87,50 %	4.000,00	0	0 %	3.500,00
3062	NDA: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	534.500,00	490.401,53	91,75 %	534.500,00	447.617,45	83,75 %	42.784,08
3070	BIOHAZ & BSE-TSE: Scientific co-operation with external experts	220.000,00	219.991,00	100,00 %	220.000,00	0	0 %	219.991,00
3071	BIOHAZ & BSE-TSE: Subventions for studies and evaluations	638.500,00	638.025,85	99,93 %	638.500,00	0	0 %	638.025,85
3072	BIOHAZ & BSE-TSE: Travel / subsistence and indemnities expenses for the members of the Panel and its Working Groups	690.000,00	642.806,23	93,16 %	690.000,00	542.013,27	78,55 %	100.792,96
3081	CONTAM: Subventions for studies and evaluations	230.000,00	227.752,75	99,02 %	230.000,00	77.101,10	33,52 %	150.651,65
3082	CONTAM: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	466.000,00	406.717,59	87,28 %	466.000,00	373.537,17	80,16 %	33.180,42
3090	AHAW: Scientific co-operation with external experts	15.000,00	14.400,00	96,00 %	15.000,00	14.400,00	96,00 %	0,00
3091	AHAW: Subventions for studies	643.000,00	642.782,06	99,97 %	643.000,00	63.487,46	9,87 %	579.294,60
3092	AHAW: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	1.150.500,00	1.027.192,29	89,28 %	1.150.500,00	904.129,99	78,59 %	123.062,30
Chapter 30		9.385.500,00	8.888.597,93	94,71 %	9.385.500,00	5.654.951,22	60,25 %	3.233.646,71
3100	Scientific co-operation	195.000,00	173.778,00	89,12 %	195.000,00	163.778,00	83,99 %	10.000,00
3102	Travel / subsistence and indemnities expenses	392.000,00	367.070,09	93,64 %	392.000,00	138.768,59	35,40 %	228.301,50
3110	Data collection exposure	1.037.500,00	960.000,00	92,53 %	1.037.500,00	0	0 %	960.000,00
3111	DATEX: Subventions for studies and evaluations	754.000,00	753.026,97	99,87 %	754.000,00	54.125,19	7,18 %	698.901,78
3112	DATEX: Travel/subsistence and indemnities expenses	112.000,00	105.638,89	94,32 %	112.000,00	102.562,26	91,57 %	3.076,63
3120	Emerging risks	178.000,00	175.722,50	98,72 %	178.000,00	0	0 %	175.722,50
3122	Emerging risks: Travel/subsistence and indemnities expenses	93.000,00	77.006,83	82,80 %	93.000,00	76.614,83	82,38 %	392,00
3131	Assessment Methodology: Subventions for studies and evaluations	176.000,00	175.000,00	99,43 %	176.000,00	52.500,00	29,83 %	122.500,00
3132	Assessment methodology: travel/subsistence and indemnities expenses	4.700,00	1.338,00	28,47 %	4.700,00	1.338,00	28,47 %	0,00
3142	PRAPeR: travel/subsistence and indemnities expenses for the members of the Expert Group and its Working groups	1.189.500,00	1.069.073,42	89,88 %	1.189.500,00	887.985,69	74,65 %	181.087,73
3144	MRL: subventions for studies and evaluations	20.000,00	20.000,00	100,00 %	20.000,00	6.000,00	30,00 %	14.000,00
3145	MRL: travel/subsistence and indemnities expenses for members of the Expert Group and its Working Groups	40.000,00	38.560,25	96,40 %	40.000,00	38.560,25	96,40 %	0,00
3150	Zoonoses: Scientific cooperation with external experts	925.400,00	925.356,00	100,00 %	925.400,00	20.987,50	2,27 %	904.368,50

mb 29 01 09 item 6 doc 4 - Annual Activity Report 2008 - adopted

3151	Zoonoses: subventions for studies and evaluations	290.600,00	290.567,25	99,99 %	290.600,00	24.845,70	8,55 %	265.721,55
3152	Zoonoses: travel/subsistence and indemnities expenses for members of the Task Force and its Working Groups	287.000,00	265.385,50	92,47 %	287.000,00	258.224,82	89,97 %	7.160,68
Chapter 31		5.694.700,00	5.397.523,70	94,78 %	5.694.700,00	1.826.290,83	32,07 %	3.571.232,87
3200	Advisory Forum Plenary	315.000,00	303.344,53	96,30 %	315.000,00	209.483,27	66,50 %	93.861,26
3201	Advisory Forum WG COM	70.000,00	59.744,96	85,35 %	70.000,00	50.590,43	72,27 %	9.154,53
3202	Advisory Forum WG IT	53.000,00	40.866,97	77,11 %	53.000,00	33.904,21	63,97 %	6.962,76
3203	Advisory Forum horizontal WG	25.000,00	21.864,31	87,46 %	25.000,00	18.425,05	73,70 %	3.439,26
3204	Advisory Group on Risk Communication (AGRC)	16.000,00	11.130,27	69,56 %	16.000,00	11.130,27	69,56 %	0,00
3211	SC: subventions for studies and evaluations	153.000,00	152.902,12	99,94 %	153.000,00	0	0 %	152.902,12
3212	SC: travel/subsistence and indemnities expenses for members of the Scientific Committee and its Working Groups	697.000,00	604.696,62	86,76 %	697.000,00	557.822,31	80,03 %	46.874,31
Chapter 32		1.329.000,00	1.194.549,78	89,88 %	1.329.000,00	881.355,54	66,32 %	313.194,24
3300	Stakeholder relations	45.000,00	40.199,92	89,33 %	45.000,00	28.336,19	62,97 %	11.863,73
3301	Crisis support	43.000,00	1.125,00	2,62 %	43.000,00	675,00	1,57 %	450,00
3302	International & Institutional Liaison	63.000,00	56.921,76	90,35 %	63.000,00	46.722,35	74,16 %	10.199,41
3310	Pre-Accession	500.000,00	402.720,81	80,54 %	500.000,00	295.738,73	59,15 %	106.982,08
3320	Strategy & Prospective	88.000,00	84.347,00	95,85 %	88.000,00	0	0 %	84.347,00
Chapter 33		739.000,00	585.314,49	79,20 %	739.000,00	371.472,27	50,27 %	213.842,22
3400	Media Relations	63.463,00	59.794,77	94,22 %	63.463,00	17.429,57	27,46 %	42.365,20
3410	Web Development	45.000,00	44.250,62	98,33 %	45.000,00	250,62	0,56 %	44.000,00
3411	Webstreamings (all)	248.388,00	239.592,87	96,46 %	248.388,00	192.719,61	77,59 %	46.873,26
3420	Public Conferences & Events	157.659,00	127.796,15	81,06 %	157.659,00	74.769,41	47,42 %	53.026,74
3421	Scientific Conferences & Events	368.616,00	280.942,55	76,22 %	368.616,00	215.416,52	58,44 %	65.526,03
3422	Press/Media Conferences & Events	71.640,00	40.245,02	56,18 %	71.640,00	27.945,39	39,01 %	12.299,63
3430	Publications	863.105,00	745.191,74	86,34 %	863.105,00	377.382,10	43,72 %	367.809,64
3440	Publicity/Marketing Material	77.000,00	76.985,31	99,98 %	77.000,00	72.340,31	93,95 %	4.645,00
3450	Evaluation	182.000,00	180.580,25	99,22 %	182.000,00	55.835,25	30,68 %	124.745,00
3460	Communication Support Activities	4.129,00	4.128,50	99,99 %	4.129,00	4.128,50	99,99 %	0,00
Chapter 34		2.081.000,00	1.799.507,78	86,47 %	2.081.000,00	1.038.217,28	49,89 %	761.290,50
3501	IT Data Collection	966.300,00	966.227,45	99,99 %	966.300,00	300.076,24	31,05 %	666.151,21
3502	Networking of organization	73.000,00	72.300,00	99,04 %	73.000,00	40.298,50	55,20 %	32.001,50
3503	Dedicated IT systems to support the operations	608.050,00	607.852,95	99,97 %	608.050,00	386.281,45	63,53 %	221.571,50
3511	Quality Management / Studies	48.450,00	47.050,00	97,11 %	48.450,00	9.410,00	19,42 %	37.640,00
3512	Library: access to databases / documents	264.000,00	249.479,28	94,50 %	264.000,00	157.305,72	59,59 %	92.173,56
3513	Mission of staff related to operational duties	1.003.000,00	999.992,84	99,70 %	1.003.000,00	999.988,06	99,70 %	4,78

mb 29 01 09 item 6 doc 4 - Annual Activity Report 2008 - adopted

3514	Shuttles	870.000,00	870.000,00	100,00 %	870.000,00	724.028,79	83,22 %	145.971,21
3515	Archives and scanning	2.000,00	0	0 %	2.000,00	0	0 %	0
3520	Translation	538.000,00	538.000,00	100,00 %	538.000,00	498.743,57	92,70 %	39.256,43
3521	Interpretation	2.000,00	0,00	0,00 %	2.000,00	0	0 %	0,00
Chapter 35		4.374.800,00	4.350.902,52	99,45 %	4.374.800,00	3.116.132,33	71,23 %	1.234.770,19
Title 3		23.604.000,00	22.216.396,20	94,12 %	23.604.000,00	12.888.419,47	54,60 %	9.327.976,73
GRAND TOTAL		66.400.000,00	64.226.083,19	96,73 %	66.400.000,00	48.725.953,39	73,38 %	15.500.129,80

Annex 2: Establishment Plan

The distribution at year end of staff by activity is as follows:

Activity	Officials & Temporary Staff	Contractual Agents	National Detached experts	Total
A.1 Provide scientific opinion and advice to the European Commission, the European Parliament and the Member States	147	31	7	185
A.2 Enhance risk assessment methodologies in Europe	49	11	3	63
A.3 Communicate scientific advice and dialogue with interested parties	39	8	3	50
A.4 manage and provide administrative support	83	14	0	97
TOTAL	318	64	13	395

With regards to the 335 officials and temporary agents foreseen in the Establishment Plan, 17 posts were vacant at the end of the year, giving an execution rate of 95%). The majority of these vacancies are expected to take place in January and February 2009. A total of 8 new agents will join in January 2009 (2 temporary agents and 6 contractual agents).

Annex 3: Declaration of assurance

I, the undersigned,

Executive Director of EFSA

In my capacity as authorising officer,

- Declare that the information contained in this report gives a true and fair view.
- State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of legality, regularity and sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the work of the internal audit capability, the observations of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for the years prior to the year of this declaration.

- Confirm that I am not aware of anything not reported here which could harm the interests of the Authority, with the exception of the probable delay in the delivery and availability of the final seat of EFSA. That delay may have indirect financial repercussions insofar as it would require EFSA to allocate more financial resources than anticipated for the payment of rents in the coming years.

Parma, 11 February 2009

Signed by:
Catherine Geslain-Lanéelle,
Executive Director

Annex 4: Report on the Implementation of the Internal Control Standards

The implementation and follow-up of the state of play of the internal control standards were conducted according to the milestones of the ICS workplan for 2008:

New revised ICS SEC (2007) 1341

The internal control standards were revised on 16 October 2007 (SEC(2007)1341) by the Commission. Their numbers were reduced from 24 to 16. These **new standards were adopted by EFSA** and implemented following a presentation to all staff in May 2008. These new standards, applicable to EFSA, have been fully implemented.

Implementation of Internal Control Assessment Tool (ICAT) 2007 survey

The implementation of the conclusions of the 2007 ICAT survey was conducted in 2008. The purpose of this survey was to measure the compliance and effectiveness of the internal control standards within EFSA. The results of the survey were communicated to the Executive Director on February 2008 and presented to all staff on May 2008. The areas where effectiveness was not considered satisfactory were integrated in the 2008 follow-up in order to improve the internal control culture at EFSA.

Exception request report

From January 2008 the automated workflow aimed at recording the exception requests was fully operational. The annual report on exception requests (ICS N°8) provided to the Executive Director shows that the number of exception requests approved in 2008 (237) decreased by comparison to the year before (241) as well as the amounts at stake (EUR 0.5 million in 2008 versus EUR 0.9 million in 2007).

ICS meetings with Units

In the framework of the workplan 2008, meetings were organised with the Units in order to increase ownership culture and improve effectiveness of the internal control system. In addition to that, specific meetings were held with Head of Units on topics like the importance of ICS *"Business continuity"* procedure, one of the areas retained by the ICAT survey.

Procedures and communication

Significant efforts were made to make procedures available for all staff; i.e. availability on Intranet of financial and procurement procedures, guides and templates. Staff was informed or reminded about these procedures, guides and other useful documents and trainings were regularly organized. In parallel, the Standard Operating Procedures are worked on and a complete repository is being created for these operating procedures.

High Level Risk Assessment

The conclusions of the High Level Risk Assessment workshop held in October 2007 were integrated in the workplan 2008. A similar workshop was held in December 2008 with an enlarged EFSA audience. All Heads of Units participated in the workshop which allowed better dissemination and ownership of the risks identified. The conclusions of the workshop conducted by Deloitte will be worked on in 2009.

IAS recommendations

The Internal Audit Service (IAS) performed a specific audit on Communication activities in February 2008 and issued 7 recommendations to which EFSA replied. A follow up audit from IAS to close those recommendations is foreseen.

Quarterly review of ICS State of Play

The implementation and progress in the state of play for the internal control standards are followed-up and updated quarterly with specific actions and deadlines for each of the 16 internal control standards.

The state of play of the 16 internal control standards at 2008 year end is as follows:

The implementation of the following 13 standards was achieved.

Standard	Situation
1- Mission	Job descriptions were completed and are available within the CDAC document. Additional efforts to harmonize them are being undertaken. Information for staff about their unit/dept. mission statement is included in the CDAC document
2 – Ethical and organisational values	<p>Administrative guidance is distributed to all newcomers.</p> <p>Staff Welfare Policy in EFSA will be available from 2009 onwards</p> <p>New ICS 16 folder is available on the intranet where ICS documentation is readily available. Presentation of new ICS 16 by units was completed.</p> <p>Human Resources information sessions for all staff on different matters are regularly organized</p> <p>Presentation of financial procedures within the Finance & Procurement Network and ad-hoc meetings such as the Joint Science Meetings.</p> <p>Presentation of financial department to newcomers. New set of information packages including ICS, Procurement/Grants and pre-paid, prepared by Finance unit in June 2008.</p> <p>Note on irregularities dated 26/01/2006 and communicated to all staff. The note is readily available in the ICS folder on the intranet.</p>
3 – Staff allocation and Mobility	<p>New Internal Mobility procedure is in place since 01/03/2008.</p> <p>Statistics on leavers, contract renewal, monitor of internal moving as well as indicators on turnover of staff and benchmarking are done regularly.</p>
4 - Staff evaluation and development	<p>A new training officer was nominated in December 2007.</p> <p>An updated training catalogue is sent to all staff on a regular basis.</p> <p>SI2 training for new AO's to comply with Charter of AO requirements are organized each year.</p> <p>Finance Procurement Network and associating trainings are frequently proposed.</p> <p>Organization of Semi-intensive language courses by training cell in the</p>

	<p>context of the third language knowledge.</p> <p>The staff appraisal and staff performance system was launched in 2007. Evaluation of staff was done end 2007.</p> <p>CDAC survey was launched by HR department and the process improved for the evaluation 2008.</p> <p>Staff survey was launched by HR in November 2008 and the results communicated to all staff.</p>
5 – Objectives and performance indicators	<p>Reviewing of objectives and performance indicators :</p> <ul style="list-style-type: none">• KPI's were reviewed in March 2008 and a new set of performance indicators is reported to the Management Board.• The EFSA's Annual management plan containing the objectives and targets with the associated performance indicators is approved each year by the Management Board• The strategic plan 2009 – 2013 and the ensuing Multi-annual programming is being put into motion• The detailed workplan, being part of the Management Plan, contains the objectives for all EFSA activities
6 – Risk management process	<p>High level risk assessment workshop was done in December 2008 and identified the risks in relation with EFSA's main activities.</p> <p>Workshop on High Level IT risk assessment, testing of the identified risks will be done in January 2009.</p> <p>A crisis exercise was done with EFSA's stakeholders in April 2008 et the Istituto Superiore di Sanita in Rome</p> <p>Several <i>ex post</i> controls were completed in 2008 (including for example the fields of Business continuity, procurement, financial shortcomings, and training).</p>
7 – Operational structure	<p>The guidance for and definition of sensitive functions applicable in EFSA was approved by the Executive Director in January 2009.</p> <p>Decision of the Executive Director (ED) regarding new delegations is updated on a regular basis.</p> <p>New authorizing officers by delegation signed the <i>charter of AO's</i></p> <p>Updates of SI2 rights are done on a regular basis as well as the filing of specimen of signature for all Financial Initiating Agents (FIA). The access to SI2 is done to FIA only after training on SI2.</p>

	Access to order workflow, Mission, Shuttle, Catering, translation is also given after suitable training.
9 - Management supervision	<p>Sessions of management training were organized in order to enhance the management capability and supervision.</p> <p>Dedicated sessions within the framework of the Career Development and appraisal cycle are organized for management and reporting officers.</p> <p>Training for the Authorising officers aimed at improving the financial supervision ability of the staff having received delegation from the Executive Director.</p> <p>The number and scope of the ex-post controls was increased in 2008 by comparison to 2007.</p>
10 – Business continuity	<p>Note signed by Acting Executive Director on 26/01/2006. Back-up is in place to ensure continuity of service.</p> <p>Explanation about Business continuity procedures given to heads of units and especially to new head of units joining EFSA.</p> <p><i>Ex-post</i> control was undertaken on monitoring the business continuity procedure and the transfer procedure in particular when a staff member leaves EFSA.</p>
12 – Information and communication	<p>Minutes of the Management Team Meeting are communicated to all staff.</p> <p>The procedure for recording and correction of internal control weaknesses is approved by the Executive Director.</p> <p>An Internal communication officer was hired in order to further develop the internal communication in a growing EFSA.</p>
13 – Accounting and financial reporting	<p>Accounting procedures are available on the intranet</p> <p>Budget execution and financial reporting is provided monthly by the Finance unit.</p> <p>Reporting tools and dedicated reports or statistics are available for various areas including experts, mission reimbursements and operational activities.</p>
15 – Assessment of Internal Control Systems	Declaration of assurance by the Executive Director is completed annually and annexed to the Annual Activity Report.

Audit Committee meetings are regularly held. The Audit Committee members closely monitored the progress made on the action plan following the IAS and the CoA reports and analysed the various audit reports and action plans performed during the year by the internal auditor. They also monitor the progress on the Audit Work Plan.

ICAT survey was completed in October 2007 and will be repeated in 2009.

In 2008 meetings were organised with all EFSA units to increase the internal culture related to ICS. Such meetings are also carried out with new appointed head of units.

The state of play and the implementation of the Internal Control Standards are follow-up quarterly.

16 – Internal Audit Capability

The Internal Auditor joined EFSA in September 2008 and delivered audit reports according to the audit work plan established at the time.

Audit Committee endorsed the new framework for the internal control standard (ICS 16)

Auditing of science units started in May 2008

The Internal Audit Service (IAS) performed a specific audit on Communication activities in February 2008 and issued 7 recommendations to which EFSA replied. A follow up audit from IAS to close those recommendations is foreseen.

The following three standards were partially achieved and further actions are required to achieve full compliance.

8 – Processes and procedures

The New expert compensation guide is Readily available on intranet.

Financial procedures are available on Intranet and updated regularly. Procurement and grant guidelines, manuals and procedures are available on the intranet.

Mid-year reporting on exceptions is done by semester, with the list of "exception requests" in annex, as well as a list of exception requests by department with the indication of amounts by category. Annual report about "exception requests" is provided to the Executive Director. The electronic workflow for Exception requests was fully operational in 2008.

IT procedures are adequately documented and the COBIT exercise

	<p>done on a regular basis.</p> <p>Standard Operating Procedures are being regrouped and re-organized in order to improve their communication and full understanding. This will only be achieved in 2009.</p>
11- Document management	<p>Filing and registration plan is still to be finalized.</p> <p>Archiving survey was completed end 2007 already in order to implement a suitable archiving plan.</p> <p>Automatic registration and mailing allocation system (chrono-in) is in place since October.</p>
14 – Evaluation of activities	<p>Business continuity plan (BCP) and disaster recovery plan were performed by Gartner company.</p> <p>Evaluation on IT risks – COBIT (Control Objectives for Information and related Technology) provides good practices across a domain and process framework and presents activities in a manageable and logical structure. COBIT strongly focuses on control.</p> <p>A global evaluation exercise will be conducted in cooperation with the Commission and the other agencies in 2009.</p>

Annex 5: List of Negotiated Procedures

In 2008, 8 negotiated procedures under Art. 126 a-g or Art 127 a-d of the Financial Regulation were signed. They mainly concern IT services (EUR 1.20 million), Infrastructure (EUR 0.23 million) and Science (EUR 0.13 million)

No	Contractor	Subject of the contract	Amount in the contract
Negotiated procedures under Art. 126 a-g or Art 127 a-d of EU FR - to be presented in Annual report on negotiated procedures			
1	Technical University of Denmark	Additional services not included in the initial contract with ref. CT/EFSA/2006/FLAVIS/2006/01 for compiling information and working out proposals for the safety evaluation of flavouring substances used or intended for use in or on foodstuffs in the framework of Commission Regulation (EC) n° 1565/2000 and maintaining a flavourings database	€ 48.000,00
2	PC-WARE Information Technologies BV	Negotiated procedure in anticipation of the early renewal of the service due to higher consumption than expected.	€ 500.000,00
3	Vodafone	Mobile telephony and data services MTDS	€ 700.000,00
4	Elsevier Ltd. UK	Report on GMO PLANTS	€ 14.250,00
5	Elsevier B.V. The Netherlands	Printing Prev VET MED Bluetongue	€ 12.875,00
6	VOSE SOFTWARE BVBA	Animal agriculture and food safety risk analysis training courses	€ 45.000,00
7	Teckal S.p.A.	Manutenzione di fabbricati di tipo civile e di infrastrutture edificio Fratti (Bridge contract)	€ 10.206,16
8	Esiet S.r.l.	Lavori edili, di genio civile, d'impiantistica e meccanica, riguardanti la costruzione, ristrutturazione e manutenzione di fabbricati di tipo civile, industriale e di infrastrutture annesse	€ 220.000,00

Annex 6: Glossary of Abbreviations

ADI – Acceptable daily intake
AOEL – Acceptable operator exposure level
AFC – Panel on food additives, flavourings, processing aids and materials in contact with food
AHAW – Panel on animal health and welfare
AI – Avian Influenza
ANS Panel – Panel on food additives and nutrient sources added to food
ASEAN – Association of Southeast Asian Nations
BIOHAZ Panel – Panel on biological hazards
BRIC countries – Brazil, Russia, India and China
BSE – Bovine Spongiform Encephalopathy
CEF – Panel on food contact materials, enzymes, flavourings and processing aids
CONTAM Panel – Panel on contaminants in the food chain
COPHS – Chief Officers of Plant Health Service
CRL – Community Reference Laboratory
CVO – Chief Veterinary Officer
CWD – Chronic Wasting Disease
ECDC – European Centre for Disease Prevention and Control
ECB – European Chemicals Bureau
ECHA – European Chemical Agency
EEA – European Environment Agency
EFSA – European Food Safety Authority
EMA – European Medicines Agency
EMFEMA – International Association of the European Manufacturers of Major, Trace and Specific Feed Mineral Materials
ENVI – The European Parliament Committee for Environment, Public Health and Food Safety
EPO – European Patent Office
FDA – Food and Drug Administration (US)
FEEDAP Panel – Panel on additives and products or substances used in animal feed
FEFANA – EU Association of feed additives and premixtures operators
FELASA – Federation of European Laboratory Animal Science Associations
FSANZ – Food Standards Australia New Zealand
GBR – Geographical BSE-Risk
GMO Panel – Panel on genetically modified organisms
IFAH – International Federation for Animal Health
ILSI – The International Life Sciences Institute
IPPC – International Plant Protection Convention
JRC – Joint Research Centre
MRL – Maximum Residue Levels
NDA Panel – Panel on dietetic products, nutrition and allergies
NGO – Non-Governmental Organisation
OIE – Office International des Epizooties
OECD – Organisation for Economic Co-operation and Development
PLH – Panel on Plant Health
PPR Panel – Panel on, plant protection products and their residues
PRAPeR – Pesticides Risk Assessment Peer Review Expert Group
QMRA – Quantitative Microbiological Risk Assessment
QPS – Qualified Presumption of Safety
RASFF – Rapid Alert System for Food and Feed
SC – Scientific Committee (EFSA)
SOP – Standard operating procedure
SSC – Scientific Steering Committee
TSE – Transmissible Spongiform Encephalopathy
USDA – United States Department of Agriculture
WHO – World Health Organization